

IMMUNIZATION PRACTICES IN PHYSICIANS'
OFFICES ON THE AVALON PENINSULA OF
NEWFOUNDLAND

CENTRE FOR NEWFOUNDLAND STUDIES

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**IMMUNIZATION PRACTICES IN PHYSICIANS' OFFICES
ON THE AVALON PENINSULA OF NEWFOUNDLAND**

BY

©CATHERINE O'KEEFE

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ABSTRACT

The immunization needs in Newfoundland and Labrador are currently met through a mixed delivery system. Immunization is performed through the Regional Health and Community Services offices, approximately 60% and private practice physicians, approximately 40%. This study assessed immunization practices in private physicians' offices with a focus on storage, handling and documentation compared with National Advisory Committee on Immunization (NACI) Guidelines. One of the key aspects of storage and handling is the maintenance of the cold chain. The cold chain is the process of maintaining vaccine at the optimum temperature from the time it is manufactured until it is administered. Since the inception of the cold chain concept, methods to assess and promote proper vaccine storage and handling have been developed.

This study has a quasi-experimental, pre and post intervention design. The study group consisted of solo and group private practice physicians who provide childhood immunizations in urban and rural practices on the Avalon Peninsula in the Province of Newfoundland and Labrador. Starting in March 1998, the researcher contacted 37 offices representing 89 physicians to participate in the study.

The study consisted of an office visit during which information was collected

concerning the practice for handling vaccine. This information was collected through a questionnaire, observation of the storage area and documentation of the refrigerator temperature. The intervention included the provision and discussion of National and Provincial guidelines for storage and handling of vaccine. A second visit six to eight months later assessed change in practice post intervention.

Of the 37 available offices, 27 (73%) participated in the study representing 89 physicians; all offices visited met at least 18 of the 24 guidelines. Vaccine was stored in the body of a refrigerator in 95% of the participating offices, 37% of the offices had a thermometer in the refrigerator, and less than 20% used thermal transport bags. Documenting the refrigerator temperature on a regular basis was only done in one office. Post intervention visits indicated little change in practice. This study has collected baseline data about physicians' practices and has given some data as to what is effective in encouraging physicians to maintain the cold chain.

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DEDICATION

My parents had always been proponents of “do your best”. I dedicate this work to Rose A. and Francis R. Kennedy with many thanks for the early lessons of life.

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GLOSSARY

Antigen – A substance (protein, polysaccharide, glycolipid, tissue transplant, etc.) that is capable of inducing a specific immune response (Last, 1995).

Antibody – Protein molecule formed by exposure to a “foreign” substance, for example, in immunization this “foreign” substance is a vaccine (Last, 1995).

Attack Rate – The cumulative incidence of infection in a group observed over a period during an epidemic (Last, 1995).

Cold Chain – The process of maintaining vaccines at temperatures between 2°– 8° C from the manufacturer to the point of injection, through proper storage and handling (Last, 1995).

Efficacy – The extent to which a specific intervention, procedure, regimen, or services produces a beneficial result under ideal conditions (Last, 1995).

Herd immunity – Resistance of a population to the invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group (Benenson, 1995, p. 536). For example, in the case of measles, a very infectious disease, the coverage rate must be very high (95%) to provide herd immunity. To achieve such high levels, the vaccine must be at its optimum efficacy when it is given (Benenson, 1995).

Immunization – Protection of susceptible individuals from communicable disease by administration of a living modified agent (e.g. Yellow Fever), a suspension of killed organisms (e.g. pertussis), or an inactivated toxin (e.g. tetanus). This definition has been

expanded in the 1980s and 1990s with the introduction of polysaccharide vaccines (e.g. *Haemophilus influenzae b*) and genetically engineered vaccines (e.g. hepatitis B) (Canadian Immunization Guide, 1998).

Temperature Monitors – Devices developed to monitor the temperature of an enclosed space over a specific period of time.

Universal Immunization Programs – Programs that are developed to provide vaccines for a target group of people. For example, measles is a disease that has the greatest morbidity and mortality in young children. Therefore, a universal immunization program would vaccinate all young children, providing protection from disease to all members of society (Last, 1995).

Surveillance – Surveillance is described as “the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control” (Last, 1995, p. 163). Surveillance generates data which allows the measurement of the effectiveness of a vaccine (Last, 1995).

Vaccine Refrigerator – A refrigerator supplied with electronically monitored temperature controls.

LIST OF ABBREVIATIONS

LCDC – Laboratory Centre for Disease Control

WHO – World Health Organization

NACI – National Advisory Committee on Immunization

EPI – Expanded Program on Immunization

PAHO – Pan American Health Organization

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CHAPTER 1

INTRODUCTION

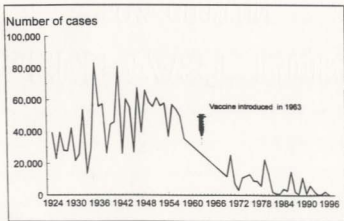
In Newfoundland and Labrador childhood immunization programs are delivered by physicians and public health nurses. The effectiveness of these programs is related to the quality of the practice of those who implement them. The focus of this study is the storage and handling of vaccines by physicians on the Avalon Peninsula of Newfoundland and Labrador. The storage and handling of vaccines were assessed against national guidelines, and this study will provide data on these practices and their compliance with national guidelines. The introduction will set a background by providing an overview on the importance and the history of immunization and why storage and handling of vaccines is an issue.

1.1 The Importance of Vaccination Programs

The introduction of vaccines has had a dramatic impact on the health of the world's population. Vaccines protect the individual from disease and, through universal immunization programs, prevent the spread of disease (Hilleman, 1989; Levine et al., 1998). Since the 1800s morbidity and mortality resulting from infectious diseases have decreased, as a result of immunization (Plotkin & Plotkin, 1994). The decrease in disease is evident when reviewing the epidemiology of vaccine preventable diseases over the past

over the past 50 years. Several of the diseases which were common in early childhood, including measles, mumps, rubella, diphtheria, tetanus and polio, are today seldom seen in North America (MacDonald, 1998). For example, the epidemiology of measles has dramatically changed since the introduction of measles vaccine in the early 1960s. This decrease in morbidity is shown in Figure 1.1.

Figure 1.1 **Reported cases of Measles, Canada, 1924 to 1996**



Note. From Canadian Paediatric Society. (1998). Canadian National Report on Immunization, 1997. *Paediatrics and Child Health*, 3 Supp B, 19B. Cases not reported between 1959 and 1968.

The decrease in morbidity is followed by a decrease in complications and mortality. This not only results in less human suffering but also in cost-savings (Casto & Brunell, 1991). This key method of primary prevention is one of *the* most cost-effective public health measures, as the cost of the disease and its complications is far greater than the cost of universal immunization programs (Tengs et al., 1995).

1.2 An Historical Review of Vaccine Development

Edward Jenner developed the first vaccine in 1796. A rudimentary vaccine for smallpox introduced a revolutionary concept of disease prevention. This process, known as variolation, actually introduced dried pus from a human lesion caused by cowpox, a virus closely related to the smallpox virus, into the patient (Plotkin & Plotkin, 1994). The medical community and the general public witnessed modified or less severe illness in those who had been immunized (Levine et al., 1998). From the late 1870s through to the early 1900s several others, including Robert Koch and Louis Pasteur, advanced vaccine development (Plotkin & Plotkin, 1994). In 1885, Pasteur generated a live attenuated vaccine for rabies, and this was the first laboratory developed vaccine. Killed vaccines for typhoid, cholera and plague were developed in 1896 and 1897. Vaccines for diphtheria, tetanus, pertussis and influenza were developed through the early 1900s.

In 1945, the Government of Newfoundland initiated its first childhood immunization program, which protected against diphtheria and tetanus. One year later the program was expanded to include the pertussis vaccine. During 1955, polio

vaccine was added to the schedule. These vaccines were provided with separate injections with the exception of polio, which was a liquid, oral vaccine. A combined vaccine was introduced in 1960 to protect against diphtheria and tetanus and pertussis. The introduction of measles vaccine in 1965 was followed in 1971 with rubella vaccine. By 1972, these vaccines were delivered as a combined vaccine, MR. In 1974 mumps was added to the MR to create MMR (measles, mumps and rubella) vaccine which is still in use in 2000. See Appendix A for a detailed history of the introduction of immunization in Newfoundland and Labrador (R. Lewis, personal communication, 1998).

The trend to combine vaccines has continued as this method has lower delivery costs and reduces trauma to the individual. The combined vaccines in use in Newfoundland and Labrador at the time of this study include Pentacel™ and MMR II™. Pentacel™, which is given at ages two, four, six and 18 months, protects against diphtheria, pertussis, tetanus, polio and haemophilus influenzae b. MMR II™ is delivered at 12 and 18 months and protects against measles, mumps and rubella (Department of Health and Community Services, 1997).

1.3 Why Proper Storage and Handling is Important

Two aspects of surveillance are vital in evaluating the effectiveness of an immunization program: a) who is being immunized, and b) who is getting the disease? If

a person who has been immunized is getting the disease, why is this person susceptible after he/she has received the vaccine? Several studies have established that vaccine failure is an issue (Hutchins et al., 1990; Mast et al., 1990), but few studies have assessed the causes of the failure (Lerman & Gold, 1971; Krugman et al., 1974). Ground breaking studies, which are described in the literature review, have established that one of the more significant risk factors contributing to vaccine failure is a break in the cold chain (Cheyne, 1989; Cheriyan, 1993).

The cold chain is the process of maintaining vaccines at temperatures between 2°-8° C from the manufacturer to the point of injection, through proper storage and handling. The recommended temperature is the range that is suitable to perfect viability of a specific vaccine. The cold chain is described by the World Health Organization (WHO) as the “backbone” of immunization programs and is as much a concern in the developed countries as it is in the developing countries (WHO, 1997).

The importance of proper storage and handling was stressed in Canada (Health Canada, 1995) when guidelines for storage and handling of vaccine were released. The rationale for these guidelines was derived from studies that highlighted major deficiencies in cold chain maintenance in Canada (Health Canada, 1995). The guidelines were developed as a result of a collaborative effort of experts in the field and then brought to the National Immunization Conference participants in December 1994 for comments and were released in June 1995 (see Appendix B).

An appreciation for the importance of immunization and the realization that the

storage and handling of vaccines should be an integral part of this process has led some researchers to study the cold chain process. Since the late 1980s several studies (Bishai et al., 1992; Casto & Brunell, 1991; Cheyne, 1989; Daniels & Naus, 1994) have assessed various parts of the cold chain, especially how and why it may fail. To date, there have not been any assessments of this kind done in Newfoundland and Labrador.

1.4 Purpose of the Study

The first purpose of this study is to assess the storage and handling practices of vaccines in physicians' offices on the Avalon Peninsula of Newfoundland and the second purpose is to see the effect of an intervention intended to improve this practice. It is intended to promote improvement in compliance with the guidelines.

1.5 Hypothesis

1. Storage and handling practices of vaccines in physicians' offices do not meet the recommended guidelines provided by the National Advisory Committee on Immunization, specifically those guidelines that are appropriate in a physician practice setting.
2. A planned intervention, provided through a personal visit, would improve the vaccine storage and handling practices.

1.6 Research Objectives

The specific objectives of this study are:

- To contact and request an interview with all offices where physicians provide childhood immunizations on the Avalon Peninsula.
- To visit participating offices and complete a questionnaire and assessment of the vaccine storage space.
- To conduct an intervention with the person responsible for vaccine use in participating offices and provide information on recommended storage and handling of vaccines.
- To revisit the participating offices and evaluate the effects of the intervention.
- To compare the initial practices with the practice four to eight months post-intervention.
- To compare the assessed practice with the national guidelines established by the Laboratory Centre for Disease Control in 1995.

CHAPTER 2

LITERATURE REVIEW

The literature review consists of a summary of the available information on the importance of immunization and the available studies on the assessment of the cold chain. Several studies regarding broad-based immunization programming have been cited in the introduction and will be reviewed briefly here. The topics involved in an assessment of the cold chain are subdivided beginning with an initial section on vaccine development. The second section provides an overview of the benefits of immunization and the third the importance of the cold chain, including the link between the occurrence of disease in immunized persons and improper storage and handling of vaccines. Improving vaccine stability is the basis of section four, which is discussed as an option to support, not to replace, the cold chain. The Canadian guidelines for storage and handling and their development are discussed in section five and the literature review closes with a section on physician compliance with the guidelines and peer review.

2.1 Vaccine Development

Vaccines provide protection from disease, and when administered to a person

who is non-immune, the person's body responds to the vaccine by developing antibodies to that particular disease (Levine et al., 1998). The effectiveness of immunization depends upon the efficacy of the vaccine, how it has been stored, how it has been administered, and the level of protection it can provide. Infection occurring after immunization is due to either primary or secondary vaccine failure. Primary vaccine failure is due to the lack of seroconversion following vaccination (Mast et al., 1990). Serological evidence may wane but protective response remains. Secondary vaccine failure can be described as an initial protective response, which wanes over time. Either type of vaccine failure may be the result of a vaccine that is effective but does not give lifelong immunity. This may occur with an improperly stored vaccine, or it may occur as a natural individual response (Krugman et al., 1974; Lerman & Gold, 1971).

To ascertain that vaccines are efficacious and safe prior to licensing, they undergo testing through clinical trials. A clinical trial is the process of testing the efficacy and safety of a drug, in this case vaccine, and providing data on how the optimum effect can be reached (Levine et al., 1998). Human clinical trials are specific in testing for safety, efficacy on the target group and efficacy in the population at large. For each vaccine, the product monograph provides specific administration instructions for a preferred site, dose by weight or age, route, timing for a series and optimum storage temperature. When all the conditions are met, a specific percentage of those immunized should have protection from the disease. For example when all conditions are ideal the expected response rate for measles vaccine is 95-97 % (Levine et al., 1998).

2.2 Benefits and Successes of Immunization

Immunization programs have frequently been cited as one of *the* best examples of cost effective prevention programs. In *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness* (Tengs et al., 1995), childhood immunizations rate as six of 56 items which have a less than or equal to zero cost for a life saved. The cost of universal immunization programs is minimal or less than the cost of treating the disease and the complications. There is no doubt that vaccines prevent disease, morbidity and mortality (Last, 1995; Plotkin & Plotkin, 1994).

There are about 50 vaccines in use today with the more common vaccines used for universal childhood and adult immunization programs. The list of vaccine preventable diseases is ever increasing. As new vaccines are developed they provide the benefit of protection from disease morbidity and mortality that is highly cost effective (Levine et al., 1998).

The World Health Organization has included the prevention of communicable diseases and immunization in its *World Health Report* since its inception in 1954 (WHO, 1998). In 1997 the Pan American Health Organization (PAHO) celebrated the 20th anniversary of its *Expanded Program on Immunization* (EPI) in the Americas. This program was developed to promote universal immunization programs, to promote proper storage of vaccines used for childhood immunization, and to monitor immunization rates. In 1994 vaccines for six diseases (diphtheria, tetanus, pertussis, polio, tuberculosis and measles) had been provided for 80% of children under one year

of age throughout the world (WHO, 1997). One of the latest accomplishments of EPI is the eradication of poliomyelitis from the Americas, which was achieved in 1991, and certified in 1994 (WHO, 1997). Vaccination coverage rates for polio had increased from 20% in 1977 to 80% in 1997. This increase was achieved through ongoing universal immunization programs and mass immunization campaigns which are known as National Immunization Days (NIDs). A NID is designated as a day to provide vaccine to a specific target group; for example, in December 1995 over a period of weeks, 82 million children were immunized in India (WHO, 1997).

2.3 Cold Chain – A Vital Part of Immunization

Each year the WHO releases a report on the state of the world's health and includes the rate of immunization coverage, immunization programs such as the polio national immunization days, and storage issues. In 1997, the WHO published "*The State of the World's Vaccines and Immunization*". This document gave details on challenges in providing vaccines, the specifics of the EPI, how vaccines are used world wide, and the development of vaccines. The final chapter, "*The Nuts and Bolts of Immunization*", provides complete details of delivery systems, how failures can occur, and the importance of the cold chain in providing properly stored vaccines. Some of the challenges to maintaining the cold chain include shipping to remote areas, a lack of electricity and refrigeration units.

With the development of the EPI program, the stability of vaccines becomes an

issue. Although the stability of vaccines varies depending upon the antigen contained in the vaccine, the detrimental effect of freezing on diphtheria, pertussis and tetanus vaccines and of heat on polio vaccine dictates the parameters for the cold chain. The system of maintaining the temperature of vaccines at 2°-8°C, or the cold chain, has a vital role in providing vaccines that prevent disease (Bishai et al., 1992; Briggs & Ilett, 1993; Casto & Brunell, 1991; Cheriyan, 1993; Cheyne, 1989; Levine et al., 1998; WHO, 1997).

One of the first studies to question whether the storage of vaccines had any possible link to disease in previously immunized children was undertaken in the early 1970s after an outbreak of measles in north-eastern Ohio (Lerman & Gold, 1971). Fourteen children who had been immunized by one particular physician with live attenuated measles virus vaccine had an attack rate of 17.9% compared with an attack rate of 1.2% in 46 children who had been immunized by local public health authorities. On further investigation, it was found that the measles vaccine had been stored in the physician's office, on the inside of the door of the refrigerator where temperature variations could occur with the opening and closing of the door. Measurements of the temperatures of this physician's refrigerator showed minimums between 0°-2° C and maximums between 6°-18° C. This was determined to be outside the acceptable range. These findings suggest that vaccines, when not maintained at proper temperature throughout the cold chain, might lose potency. While the authors recognized the limitation that disease could not be directly linked to the loss of potency (resulting from

incorrect storage), this raised awareness of such questions.

Others have tested vaccines from a controlled storage setting and then compared these with vaccines which have had unknown storage conditions. In one study four live-virus combination vaccines-measles, mumps, rubella, combined measles-rubella, and oral polio-were used to test the relevance of improper handling on the potency of the vaccines (Krugman et al., 1974). Vaccines in use in clinical practice were compared with a control vaccine, which had been stored at the Bureau of Biologics at 2°-8° C in an electronically monitored setting. After one year, the same lot of vaccine was recalled from nine states where it had been stored in unknown conditions. The return of the vaccine to the U.S. Bureau of Biologics occurred under proper 2°-8° C, temperatures. Findings indicated that 20 of the 107 samples (19%) showed significant loss of potency; this was extrapolated to reflect in the order of two standard deviations above or below the recommended strength. Eighteen of the 20 samples had little detectable virus, while the remaining two had no virus, and therefore could have no effect in promoting seroconversion. This work provided evidence that the potency of vaccines was affected by improper storage and that storage in local physicians' offices was less than optimal. Krugman's study did not have any data on the storage of vaccine in the community during that year; therefore the vaccine may or may not have been stored properly. The study does provide information on vaccine that had been stored in "typical" conditions.

While other studies discuss the outcome of measles outbreaks in previously immunized populations, they do not look at why these populations remained susceptible

post-immunization. Reimmunization with a second dose of measles vaccine was recommended. These studies focused on the modes of transmission and risk factors for disease (Chen et al., 1989; Hutchins et al., 1990).

2.4 Improving Vaccine Stability

In the late 1970s and throughout the 1980s vaccine stabilizers were developed that increased the vaccine's effectiveness by reducing the risk of primary vaccine failure due to improper storage and handling (Mast et al., 1983). The introduction of stabilizers to the vaccines provided products with a longer "shelf life". This may have created a false reassurance that would be one of the reasons that concern for cold chain maintenance was delayed in Canada until the 1980s. Obstacles and issues regarding heat stabilization are the focus of work in the late 1980s (Hilleman, 1989). Hilleman's research discusses obstacles to heat stabilization which include inherently unstable polymers and the fact that the chemical structures are difficult to maintain except under ideal conditions. This supports opting for the development of a cold chain, instead of depending upon the development of vaccine products with a broader range of stability. Hilleman describes how changing the structure could affect the effectiveness of a vaccine: "To be effective, these organic polymers must retain their primary and secondary structures as well as their interrelationships if their activities are to be retained" (p. 613). One limitation of Hilleman's study was that it assessed only one type of vaccine (measles, mumps and rubella), another was that the pharmaceutical company

which produces that particular vaccine released it.

2.5 Assessing the Cold Chain Practices

The potency of vaccines is affected by exposure to too much heat, light or cold (Lerman & Gold, 1971; Krugman et al., 1974; Levine et al., 1998). The cold chain, when maintained, protects vaccines from these external factors and is described by the WHO as the “backbone” of the EPI program and is as much a concern in the developed countries as it is in the developing countries (WHO, 1997, p. 155).

By the mid-1980s the term cold chain had been used to define the proper maintenance of vaccines during the distribution process (Cheyne, 1989; Cheriyan, 1993). This recommended standard of maintaining temperatures between 2 °–8° C was yet to be assessed in practice. In 1989, Hunter’s United Kingdom-based study assessed the practice of nurses and physicians in storing and handling of vaccines. A questionnaire was distributed to all of the available 36 practices in south Hampshire and Dorset, and included the following questions: Do you keep a thermometer in your refrigerator?; What type of refrigerator do you use?; What do you do with vaccines when you are defrosting the refrigerator?; How long do you keep vials containing multiple doses of vaccine? Do you give your patients vaccines to store at home? Nurses staffed many of these practices and 33 of the 36 (92%) responses indicated that they did not know the correct storage temperature and did not keep thermometers in their refrigerators. In summary, “nurses cannot be sure whether the vaccines they use are potent and whether they will provide adequate protection against life threatening diseases” (Hunter, 1989, p.

661). The author made recommendations for guidelines but no further follow up was suggested, nor was a visit made to the offices to compare the actual practice with the reported practice.

Other researchers in the United Kingdom assessed the quality of storage of vaccines in the community (Thakker & Woods, 1992). In the Manchester Health Authority region 45 offices were randomly selected and approached to participate in a survey which questioned where the vaccines were stored, who cared for the vaccines and the availability of thermometers. Of the 40 (89% response rate) respondents, less than half (16) were aware of the appropriate storage conditions, eight had maximum/minimum thermometers, but only one of these was monitored daily. This study cited the lack of knowledge of vaccine care as a contributing factor to breaks in the cold chain and expressed the need for guidelines and the training of staff. Again one limitation of this study was a lack of follow up with the offices to promote proper practice and to compare survey responses with actual practice.

Briggs & Illett (1993) in the Central Birmingham Health District studied transport temperatures. All of the available 53 general practices and six health clinics were requested to participate, and 136 questionnaires were distributed and returned (100% response rate). Vaccines were tagged with a Monitor Mark Time-Temperature Integrator Tag (TM3-M) and a questionnaire was enclosed. This tag monitored the temperature during transport of the vaccines and at the destination provided a record of the length of time the product was exposed to the recommended temperatures. The

questionnaire provided information on the mode of transport, journey time and distance and whether refrigeration was available during the transport as well as immediately upon delivery. Of the responses received, 104 of the 136 (76%) indicated that transport conditions were suboptimal. Most (82%) shipments by car were not refrigerated and (68%) did not refrigerate the vaccines on arrival. Several of the areas assessed indicated points where the cold chain had not been maintained during the transportation phase. These areas included cars without a coldbox, journeys in 21°C temperature and a lack of refrigeration upon arrival. This study did provide exact data on the temperature of vaccines during a two-week period.

By the early 1990s more work was done in the United States to promote the importance of the cold chain. It had been recognized and recommended that: "One important factor that can affect vaccine efficacy, however, is rarely discussed-how vaccines are handled during shipment and storage" (Casto & Brunell, 1991, p. 108). This paper provides an overview of the importance of the cold chain and the long-term ramifications should vaccine be improperly stored:

Inactivation of a vaccine may become apparent only after patients who are administered the product acquire the disease it was designed to prevent. Even when this happens, it is likely that the identified cases will be considered primary or secondary vaccine failures, and the role that improper vaccine handling may have played in the failure will escape scrutiny (p. 108).

The authors support adherence to the cold chain as one way of ensuring that vaccines with the expected potency will reach the target population.

A report on paediatricians' offices in Los Angeles was completed in 1992.

Forty-six primary care paediatricians were randomly selected as well as three university-affiliated hospital-based clinics and one community clinic for a sample size of 50. A telephone call was made to each office to request an office visit to assess the storage of vaccines. The participation rate for this study is not provided. A summary of results indicated that vaccines were routinely stored outside the refrigerator and stored in uninsulated containers during the practice day; “vaccine storage errors occur in paediatric offices at an unacceptably high frequency” (Bishai et al., 1992, p. 193). Only 16% of vaccine storage co-ordinators could cite appropriate temperatures and 18% were unaware that heat could harm vaccines. Temperatures were checked weekly in only 20% of the practices and vaccines were routinely stored outside refrigerators in 16%. The report concluded that paediatricians should “familiarise themselves with guidelines for optimal vaccine storage in order to minimize the potential for vaccine failure in primary care practice” (Bishai et al., 1992, p.193). The authors acknowledged that the limited number of available offices made it difficult to generalize the results but that “the high prevalence of avoidable vaccine storage errors were striking” (p. 194).

In another leading paper, Cheyne (1989) described a hypothetical journey of vaccines for the typical 12 to 18 month voyage of vaccines from production to delivery. The premise was that the vaccines are at the greatest risk as it leaves the main offices and travels out to the community, where several opportunities arise for interruption of the cold chain. Cheyne identified some experiences of loss of vaccine potency that potentially occur during the transport period including a delay of a day or two on an

international flight, delays at customs and so on. In tropical countries, the lack of ice making capability is an issue. Cheyne suggested that by identifying the weak spots in the cold chain, countries or private sector manufacturers can develop strategies to avoid these occurrences.

As recently as 1999 assessments of the cold chain practices have been completed in the United Kingdom (Finn & Crook, 1999). In this study a total of 107 questionnaires were sent (anonymously) to general practices in the United Kingdom known to employ one or more nurses, and resulted in 75 responses (73%). This questionnaire assessed vaccine handling and storage in general practices. In all but one the response came from the nurses; the exception came from a receptionist. Sixty-three of the 75 stated that the nurses were responsible for vaccine management. Over half of the practices used domestic refrigerators instead of the recommended vaccine refrigerator. Only 27 of the 75 offices used thermometers, yet 55 reported monitoring the temperature prior to an immunization session. Finn and Crook concluded that "in this particular health district, maintenance of the cold chain is not always accorded the degree of care necessary for safe practice" (p.47). The areas of particular concern included receipt and storage of vaccines, temperature monitoring control, management of vaccines during immunization sessions and disposal of partly used vaccines. The survey response was not verified by an office visit and this led to a caution regarding storage of vaccines from the authors.

One of the earliest Canadian studies (Steinmetz et al., 1981) questioned the

storage of live measles vaccine. Measles vaccine had been introduced in Canada in 1963, and a 90% reduction in the incidence of cases was subsequently reported. Outbreaks in 1979 and 1980 led to concern about the effectiveness of the vaccine when a survey showed that 60% of the 260 cases had been previously immunized with measles vaccine. Had illness occurred as a result of improper vaccine storage? In 1981, twenty immunization centres were visited without notice, including 13 paediatricians associated with the Montreal Children's Hospital, six immunization clinics and one hospital clinic. These offices were randomly chosen from a list of paediatrician's offices. The vaccine and the refrigerator temperatures were measured with specific attention to the placement of vaccine in the refrigerator. In 17 of the 20 (85%) practices studied, the vaccine had been stored at temperature levels above the recommended safety limit (Steinmetz et al., 1983). Other problems included vaccines stored in the freezer with no power back up, and vaccines left unrefrigerated for several hours at a time. The vaccines tested were the newer heat stabilized vaccines and no significant loss of potency was noted when the components were tested. This study questioned whether the lack of proper storage and handling in the past may have affected the less stable vaccines produced and used prior to 1979. If this were the case, improper storage and handling may have played a significant role in the 1979 and 1980 outbreak of measles.

Following these concerns, Daniels and Naus (1994) performed an evaluation of the cold chain in Ontario. Their study took the form of surveys and visits to audit storage practice in physicians' practices. The survey revealed that 31% of physicians'

refrigerators had temperatures outside of 2° -8° C range. Daniels and Naus also found that 20% of the vaccine refrigerators were over 10 years old and unreliable. Less than 15% of the refrigerators used a thermometer and fewer than 22% of couriers transported vaccine in insulated containers (Daniels & Naus, 1994). These cold chain concerns led to a formal cold chain evaluation. This study used temperature monitors, which indicate exposure to temperatures above 12°C. These Monitor Marks® were attached to 80 DPT (diphtheria, pertussis, tetanus) and polio vaccine packages distributed from the Ontario Public Health Vaccine Depot. The recipients were requested to telephone a toll free number on the following occasions: when the vaccine was received, if the vaccine changed clinics, when all the doses were used, and if any colour change in the cold chain monitors was noted.

A total of 76 (88%) cold chain breaks occurred during the distribution process with 98% of the breaks taking place during storage at health departments, physician's offices or clinics. Only 2% took place during transport. This was higher than the previously reported study in Durham where 57% of packages were heat exposed (Daniels & Naus, 1994, p. 99).

Daniels and Naus concluded that education of physicians was needed to improve vaccine storage and handling. As a result of this study, an education program for physicians was initiated. The program included an extensive information package on proper storage and handling, how and where to order a maximum-minimum thermometer, and established a telephone line for questions. In 1998, preliminary results of a follow-up study showed a vast improvement in vaccine storage post-education and

provision of thermometers (T. Deasey, personal communication, 1998).

British Columbia is the only other province that has assessed storage of vaccines in public health and physicians' practices. Pielak et al. (1995) described a survey of 94 physicians and 22 public health offices. While exact numbers were not presented, the summary concluded that few vaccines are properly transported and stored. This led to an awareness program for health professionals who immunize. No subsequent studies have followed the information campaign to date, but personal communication with staff in this division indicate a positive response from vaccine providers (K. Pielak, personal communication, 1997).

Other concerns about deterioration of vaccines from improper storage and handling recently came from Australia. Gold, Kemp and Osbourne (1998), in a letter to the editor of *The Australian Medical Journal*, raise concerns that while many initiatives to increase coverage rates exist, "few vaccine providers adhere to a cold chain storage, and a recent study from a metropolitan area in Australia has documented that vaccines are often subject to temperatures below freezing points" (p. 471). The unpublished studies referred to in this letter had led to the conclusion that the burden of illness increases with the susceptibility that occurs from the use of vaccines that have lost their potency. This in turn has implications for the lost income of parents or caregivers and additional costs incurred as a result of hospitalization for complications. This letter to the editor emphasized the continued concern for lack of proper storage and handling.

Most of the evidence that suggests that improper storage and handling of vaccine is a factor in the susceptibility of previously vaccinated individuals is indirect. The studies that support this theory are those which have indicated that there is loss of potency in vaccines that have been exposed outside the recommended 2°- 8° C temperature range.

In 1992 a study was initiated in British Columbia to test the effects of freezing on DPT or DPT-inactivated poliovirus vaccines and to determine if a previously used “shake test” could accurately identify vaccines that had been previously frozen. Forty single dose vials were divided: five were used as controls and stored at 2°-8°C, 20 were placed in a freezer set at -10° C, the final 15 vials were set at a temperature of - 70° C. The control vials remained unchanged in colour and viscosity. Those vials exposed to -10° and -70°C temperatures were not visibly altered. The shake test could not be used to determine whether or not vaccines had been exposed to freezing. The recommendation from this study was that “The only reliable means to determine if vaccines have been inadvertently frozen and thawed is to place temperature monitoring devices beside them during transport” (Dimayuga, 1995, p. 102). A similar study (Brazeau & Delisle, 1993) reported on experiments which indicated a loss of potency in previously frozen vaccine. These studies were referenced in the development of the National Guidelines for Vaccine Storage and Handling in Canada.

2.6 Guidelines for Vaccine Storage and Handling in Canada

In 1995, the National Advisory Committee on Immunization (NACI) released its *Guidelines for Vaccine Storage and Transportation*. The Canadian Pediatric Society, the Laboratory Centre for Disease Control and the Bureau of Communicable Disease Epidemiology endorsed these recommendations. Portions of these recommendations were published in 1995 in the *Canadian Medical Association Journal* and the *Canadian Family Physician*. In the 1996 *Newfoundland and Labrador Communicable Disease Report*, the national guidelines were adapted and printed as recommendations for vaccine storage and handling. In December 1997, NACI released its recommendations for Childhood Immunizations. These guidelines were summarized in the February 1997 *Canadian Medical Association News* issue, with a statement endorsing the immunization guidelines (Canadian Medical Association, 1997) and recommended that physicians follow NACI's guidelines for vaccine storage and the recording and reporting of childhood immunizations.

These guidelines were developed "as a general guide for consideration" (Health Canada, 1995, p. 93) and bringing them into practice would depend upon each province and territory. The Childhood Immunization Division, Bureau of Communicable Disease Epidemiology, Laboratory Centre for Disease Control, undertook the preparation of the guidelines for vaccine storage and transport in collaboration with a group of expert

advisors. The documents used in preparation of the guidelines included:

- Compendium of Pharmaceuticals and Specialties. (29th ed.) Canadian Pharmaceutical Association, 1994.
- Product Information Sheets, 1993/94. (10th ed,) WHO/UNICEF Technical Series, May 1993.
- World Health Organization cold chain information: publications, instructional slide sets, and training courses.
- Vaccine Distribution, Storage and Handling Guidelines. Mandatory Health Programs and Services, Public Health Branch, Ontario Ministry of Health. Draft Copy, September 1994.

2.7 Physician Compliance with Guidelines and Peer Review

Physician compliance with guidelines has often been low; yet guidelines and standards for practice are the norm (Studiciki et al., 1993; Goethe et al., 1997). How then can physicians be encouraged to follow guidelines? While this question was not an original part of this research, the results from physician interviews provided some insight into this area. Arif et al. (1998) evaluated physician compliance with tuberculosis treatment standards through a chart review in Pakistan in 1995. A questionnaire to evaluate physician compliance was developed, pilot tested and standardized. A chart review was conducted of all patients hospitalized with tuberculosis comparing diagnosis and treatment with the WHO standards. The researchers concluded that physician

practice “reflects poor awareness of the WHO guidelines with low compliance among physicians” (Arif et al., p. 230).

Lawler and Viviani (1997) went a step further to assess why compliance is low in the treatment of diabetes in the United States. Interviews were conducted with 295 patients with diabetes and their respective physicians. Their findings indicated that physician beliefs and practices varied greatly and provider performance of the national standards for diabetes care was low. The most common factors for this included a lack of knowledge, implementation problems, a lack of belief in guidelines, and problems with patient compliance.

In responding to physician non-compliance, some research has suggested that computer generated reminders were effective in promoting discussion of patient care (Dexter et al., 1998). Peer review was also an effective method of encouraging compliance (Grol et al., 1988; Lang, 1991).

Peer review of physicians' practice is the “review of clinical performance, when it is a form of medical audit” (Last, 1995, p. 123). Expectations of peer review include providing indicators for uniformity in practice and, at the same time, assisting in the development of general practice medicine (Grol et al., 1988). Peer review that included assessment of the cold chain was developed in Atlantic Canada in the early 1990s. This program was based on a similar program in Ontario which has been in place since 1981 (NLMA, 1991), and which provides an assessment of a physician's practices by other physicians. “This involves one or two physicians visiting an office and looking at such

things as legibility of charts, function of equipment, cleanliness and so on" (NLMA, 1991, p. 1). As peer review developed, specific topics were submitted for review. In 1993 the first group of assessments was completed (including storage and handling of vaccines). This involuntary process began with low numbers and has gradually increased, with 90 assessments completed in 1995. In the Newfoundland and Labrador Medical Association Newsletter-*NLMA Communique* (April/May, 1999), the refrigeration of vaccines and drugs is listed as one of the "deficiencies that directly affect patient care" (p. 13). The results of the assessments are not provided but it includes a statement about the importance of refrigeration and documentation of refrigerator temperature for the proper care of vaccines.

2.8 Assessing the Vaccine Distribution System in Newfoundland and Labrador in Relation to the Cold Chain

Maintaining appropriate storage and handling at a set temperature (usually 2°-8° C) from the time the vaccine leaves the producer until it is administered is known as the cold chain. To assess the cold chain in this study, one must first understand the process for distribution of vaccines to and within Newfoundland and Labrador. Public Health Nurses, with the exception of the Avalon Peninsula where public health nurses (60%) and physicians (40%) provide the service almost exclusively provide childhood immunization programs in Newfoundland and Labrador. Typically in rural areas, public health nurses provide the service through child health clinics. In the urban areas,

physicians and public health nurses provide vaccines in their respective offices. On the Avalon Peninsula 89 physicians in 37 offices provide childhood vaccines, of which the most common are MMR (measles, mumps and rubella) and DaPTP/Hib (diphtheria, acellular pertussis, tetanus, polio and haemophilus influenzae b). The process for distribution of vaccines in Newfoundland and Labrador is as follows(R. Lewis, personal communication, January, 1997):

1. Suppliers send vaccine, under monitored storage conditions, to the provincial vaccine distribution depot in St. John's. The province's Department of Health and Community Services purchase this vaccine for the immunization programs.
2. Cold storage is maintained in temperature controlled refrigerators with alarm systems in place.
3. Monthly vaccine orders are filled from the depot and forwarded in labelled, Styrofoam containers with ice packs and temperature monitors to the Health and Community Services office in each of the six regions in the province.
4. On its arrival, informed staff, who have been trained in the importance of maintaining the optimal temperature, receive the vaccines. Packing slips with temperature monitors are contained in each vaccine shipment and the temperature is verified on receipt. This packing slip is then returned to the provincial office to ensure that all shipments have reached the regional office with the cold chain maintained.
5. The regional Health and Community Services office supplies district public health offices with vaccine using Styrofoam boxes or thermal bags with ice packs. Physicians typically pick up their vaccine from the Health and Community Services office staff in paper bags or a courier ships them to the physicians' offices in a cooler equipped with ice packs.

6. In physicians' offices, household type refrigerators are used for storage.

A break in the cold chain may occur at any point, but the weakest link in the chain occurs when the vaccine leaves the regional office for the district office and from the district office to the physicians' offices. Health and Community Services offices use the guidelines outlined by the *Provincial Immunization Manual*, first issued in 1988. Physicians are notified through newsletters, letters from the local Medical Officer of Health, and through the Newfoundland and Labrador Medical Board on the proper storage and handling of vaccines (A. Roberts; R. Young, personal communication, February, 1998).

2.9 Pilot Study

The investigator conducted a pilot study in 1997 in preparation for this research. A 22-question survey was developed to assess the practice of storage and handling in public health and physicians' offices and provided an opportunity to pre-test the questionnaire. Questionnaires were mailed to 25 public health nurses and 25 physicians in the St. John's area from a listing provided by the Health and Community Services office. This questionnaire was intended to gather information on who was immunizing and how vaccines were being handled. The questionnaire included questions on demographics, on years in practice, the number of immunizations given in a week, where the vaccine was stored, whether the temperature was documented and how the vaccine

was transported when it left the refrigerator.

More than 22 of the 25 (88%) public health nurses responded to the questionnaire. Furthermore all of these respondents indicated storage and handling of vaccines which adhered to 22 of the 24 (92%) guidelines (O'Keefe, 1997, unpublished). Refrigerator storage was maintained with thermometers in place, although not all of these thermometers were maximum/minimum. The refrigerator temperatures were not being monitored nor were water bottles used to help maintain the refrigerator temperature. These measures were implemented to some degree shortly thereafter (M. Mayo, personal communication, 1997). Water bottles were installed, and monitoring and documentation on a twice-a-week basis was initiated. Insulated bags were used for the transport of vaccines to satellite clinics and a visit to these offices confirmed proper methods for storage as well as monitoring of refrigerator temperatures.

Only six of the 25 (24%) physicians responded to the questionnaire. Of the six returned questionnaires, only two were fully completed. Of the completed questionnaires the documentation of temperature was non-existent; some responses had question marks (?) placed next to a question regarding the *Canadian Guide to Immunization*, querying what this was, and when asked how vaccine was transported, the response was always in a paper bag. The responses regarding storage and handling of vaccines in physicians' offices indicated that further research was needed in this area.

2.10 Summary

The importance of maintaining the cold chain is a vital part of an effective immunization program. In short, there has been no lack of educational materials provided for nurses and physicians in support of proper immunization techniques, including the cold chain as indicated in the documents sent to health care professionals after the national guidelines were published in 1995. Much of the research to date strongly suggests that improper storage and handling of vaccines in physicians' offices is an issue which may contribute to health problems. Discussion with Medical Officers of Health for Newfoundland and Labrador and the provincial Director of Disease Control and Epidemiology supported a study to assess the storage practices in physicians' offices. To date no other studies on vaccine storage and handling have been carried out in Newfoundland and Labrador.

CHAPTER 3

METHODOLOGY

This chapter includes a description of the design, measures, and ethical considerations of this study, which has a quasi-experimental, pre- and post- intervention design. It was carried out over a period of 15 months, from February 1998 to May 1999. The sampling frame consisted of all urban and rural physicians who provide childhood immunizations and have offices on the Avalon Peninsula in the Province of Newfoundland and Labrador.

3.1 Design

In designing this study several authorities were consulted for input on the questionnaire, consent form and methods. These authorities included the College of Family Physicians, Newfoundland and Labrador Medical Board, Newfoundland and Labrador Medical Association and Health and Community Services offices in the St. John's and Eastern Regions. These groups were contacted to investigate whether past studies had been completed in Newfoundland and Labrador. No research had been done in Newfoundland and Labrador.

The pilot project in 1997, described in the literature review, was conducted involving a mail-out questionnaire. The poor response rate (24%) from the mail-out to

physician offices was a deciding factor in determining the choice of the methods for this study. An office visit would increase participation and was therefore the method of choice for data collection.

The questionnaire was developed using varied sources (Briggs & Illett, 1993; T. Deasey, personal communication, 1997; Haworth et al., 1993; Hunter, 1989; Thakker & Woods, 1992). A similar questionnaire (see Appendix D) had been used in Ontario (Daniels & Naus, 1994); portions of this were used (T. Deasey, personal communication, February, 1997). The *National Guidelines for Storage and Handling of Vaccine* (Health Canada, 1995) provided 35 guidelines of which 24 were chosen as appropriate for practice in a physician's office. The brief questionnaire was designed to be completed in the short period of time permitted in the physician's office.

The first phase of the study involved a pre-arranged, in-office visit with an opportunity to obtain consent to participate in this study, assess the vaccine storage area and complete the questionnaire. At the end of the first visit the intervention package was provided (see Appendix G) and a discussion of what changes might be required to better meet the guidelines (e.g., obtaining a thermometer and where) was undertaken. The second phase of the study was an unannounced visit six to eight months later to assess any changes since the first visit. This visit was an observation of the storage area and did not require the physician's presence.

3.2 Subjects

The areas served by the Health and Community Services in St. John's and Eastern Newfoundland were chosen because in these areas the physicians provide childhood immunizations. In rural Newfoundland and Labrador community health nurses provide an estimated 95% of childhood immunizations (Department of Health and Community Services, personal communication, 1997). A listing of the physicians who are given vaccine to provide childhood immunizations was obtained from the Health and Community Services offices in the St. John's and Eastern Regions. The list from the St. John's and Eastern Health and Community Services offices consisted of 37 offices representing 89 physicians; these were contacted beginning March 1998. All of these offices were on the Avalon Peninsula, which is the most populated area of the province with one-third of the total population according to the 1996 Census (Statistics Canada, 1996).

3.3 Instrument

The questionnaire consisted of three distinct sections (see Appendix C): the first provided demographic information; the second questioned general storage issues including the type of storage; and the third was completed through observation and measurement. These questions had been developed using the national guidelines as the "gold standard" (Health Canada, 1995).

These national guidelines provide 35 recommendations which, if followed, would allow for proper maintenance of the cold chain in vaccine storage. These are subdivided

into three headings: Knowledge and Responsibility for Vaccine Care; Storage of Vaccines in Physician Offices; and Temperature of Vaccine Refrigerators and Documentation of Refrigerator Temperatures. The recommendations for storage, which are applicable in a physician's office, are summarized in Tables 3.1-3.3. These tables provide a commentary on the method of assessing each of the guidelines (column 2) in the questionnaire (see Appendix C). One question regarding the availability of freezers was not a national guideline, but was added as this data would be of particular interest in the event that a vaccine required freezing (National Immunization Conference, 1996).

The content of the questionnaire was developed using a similar questionnaire used in Ontario (see appendix D) and several studies conducted in the United Kingdom (Briggs & Illett, 1993; Haworth et al., 1993; Hunter, 1989; Thakker & Woods, 1992). Validity of the questionnaire was obtained through peer review, review by the Medical Officers of Health and through the pilot test conducted in 1997.

Table 3.1 Assessment of Knowledge and Responsibility for Vaccine Care

Guideline	Method of Assessment
One person in the practice should be responsible for vaccines	Questioned
All persons responsible for handling vaccines should know The correct storage temperatures; should be trained in this	Questioned
Power failure procedure should be posted on the door, And this should be followed in such an event	Observed
Educational material should be available on the cold chain In all centres where vaccine is stored	Questioned
Procedures for “exposed” vaccine should be in place	Questioned
Regular maintenance of refrigerators should be Performed and records kept	Questioned
Vaccine Associated Adverse Event forms should be Completed as required	Questioned

Table 3.2 Storage of Vaccine in Physicians' Offices

Guideline	Method of Assessment
Vaccine should be stored in the main part (body) Of the refrigerator, never on the door	Observed
Vaccines should be refrigerated as soon as Possible after transport	Questioned
Refrigerator should be dedicated to vaccine storage only	Observed
Defrost if more than one centimeter of ice has accumulated	Observed
Vaccines should remain refrigerated except when in use	Questioned
Space should be left between vaccines to allow circulation Of air	Observed
Keep a sign near the electrical plug to prevent accidental Loss of power	Observed
Make sure the door is closed when not in use	Questioned
Adsorbed vaccines should be stored well away from Ice or possibility of freezing	Observed
Vaccine should be transported in insulated containers With appropriate freezer packs	Questioned
Water bottles should be used as a temperature stabilizer In the refrigerator	Observed

Table 3.3: Temperature of Refrigerators and Documentation of Temperature

Guideline	Method of Assessment
All refrigerators should have a Maximum-minimum thermometer	Questioned & Observed
Two daily readings of the refrigerator temperature Should be taken and recorded on a regular basis*	Questioned & Observed
The temperature of the storage refrigerator Should be between 2 °- 8°C	Observed
Immunization should be recorded on the patient's chart	Questioned
Immunization should be recorded and given to the Patient or parent	Questioned
A record of immunization should be forwarded to the Health and Community Services office	Questioned

*"Regular" basis would be defined as once a week to twice a month.

Recommendations in the national guidelines for transport applied mainly to large quantities of vaccines, such as shipments from manufacturers. The recommendation that vaccines should be transported in an insulated container, with an appropriate number of ice packs, was appropriate for physicians' offices and was questioned in the study.

A search of the literature and discussion with experts in the field led to one questionnaire that had been used in Ontario; no others could be located. Results of the

studies often provided a summary of the topics covered and provided the type of appropriate questions (Briggs & Illett, 1993; Haworth et al., 1993; Hunter, 1989; Thakker & Woods, 1992). The questionnaire used in this study, along with the content of questions and expected responses, was developed using *The Canadian Guide to Immunization and the Guidelines for Storage and Handling* (1995) and the questionnaire used in Ontario (see Appendix D). The pilot study had included a pre-test of the instrument used in this study and was used with minimal modifications, which met the requirements of the study and the Human Investigations Committee of Memorial University of Newfoundland.

The 22 questions were “Yes or No” (10), multiple choice responses (11) short answer (1) and an opportunity for comments at the end (see Appendix C). There was time at the end of the interview for an opportunity to discuss and clarify issues. The questionnaire covered demographics, key responsibility for the care of vaccines, storage and handling practices, and comments regarding the current system for distribution. The visit also included measuring the refrigerator temperature, observing the storage area, and providing answers to several spontaneous questions asked by the physicians and not queried in the formal portion of the questionnaire.

The second phase of the study included an unannounced visit six to eight months after the initial visit. The practices were again be assessed regarding storage and handling of vaccine with particular attention to the areas found deficient in the first visit. As consent for this visit had been signed during the first visit no prior notification was

necessary. The post-intervention or second phase visit took approximately ten minutes with questions focusing on changes in the practice. The refrigerator was observed for the deficiencies evident in the first visit, such as the availability of a thermometer, documentation of the refrigerator temperature, and the presence of water bottles.

3.4 Permission and Informed Consent

An initial telephone contact was made for the physicians' permission to conduct an interview in their office. Participation in this study was voluntary.

The first item of the interview was the informed consent form (see Appendix E). This form explained the nature, purpose and objectives of the study, was witnessed and dated by the office secretary. This consent to participate in the study included the initial visit on that day and the unannounced visit planned for Phase II four to eight months later.

3.5 Confidentiality

To maintain confidentiality, each two-page questionnaire was coded to correspond to the informed consent form. The consent form and the completed questionnaires were kept in separate files. Only one identifying factor was used to indicate if the participant was from a rural or an urban setting, which was required as part of the analysis. This information was kept in a locked drawer with identifying codes kept in a separate place. Only the investigator had access to the codes.

3.6 Risks and Benefits

The only risk to physicians, as a group, was the possible discipline that would result from the disclosure of poor handling. Through the confidentiality agreement no single practice would be identified in the results. Discipline would not come from the investigator but could come with the release of the results. The consent form included a statement which confirmed that the information gathered would be used solely for research purposes.

Possible benefits evidenced throughout the study included information for the participating physicians' offices on proper storage and handling and had the potential to improve the current practice, as well as an opportunity to discuss vaccine storage and handling.

3.7 Data Collection

3.7-1 Procedure for Phase I

A letter of introduction (see Appendix F), which was sent from the Medical Officers of Health in the St. John's and Eastern regions to all possible participants gave a brief description of the study and identified the investigator. The first telephone contact with each office was within two weeks of the sending of the introductory letter. A copy of the letter was also taken to the interview in the event that verification was required.

A total of 40 offices were contacted by telephone. Telephone protocol (see Appendix H) was used during the telephone call to ensure consistency among the participants. The office secretary took the call and then consulted with the doctor before an appointment was made. Two offices no longer provided childhood immunizations and one office had closed before the telephone contact was made, leaving a total of 37 possible offices of the 40 first identified.

If accepted, an office interview was arranged during the telephone call and visits were made at the convenience of the office. Most often these were held at the beginning or end of the practice day or at lunchtime. Many offices had one physician or office manager who was responsible for the vaccines. The interview was conducted with that physician or manager as the representative of that practice.

Appointments were made one week to one month in advance. Several offices were busy and requested a call at a later date. These returned phone calls carried on into May, June and July, 1998. Phase I interviews took place from April 1998 to July 1998, typically with a duration of 10 to 15 minutes, and included:

- Explanation of the project and the signing of the informed consent
- Completion of the questionnaire
- General discussion around the care of vaccines
- Intervention package of information on vaccine storage and handling (see Appendix G)
- Measurement of the refrigerator temperature and the observation of the vaccine

storage area

3.7-2 Procedure for Phase II

The second visit was to assess any change in the practice of vaccine care since the initial visit. To allow the office sufficient time to obtain any necessary equipment, the investigator waited for six to eight months after the initial visit before the second visit. The questions asked during the second interview revolved around the same general points as the first interview with an added focus on the key points notably absent in Phase I. Observations of the storage area were also made at this time and included:

- Presence of a thermometer
- Presence of documentation chart for refrigerator temperature
- Presence of water bottles
- Position of the vaccine in the refrigerator (should be central and space for air circulation)

Phase II was completed in two parts: the first from October to November 1998, and the second from January to March 1999. The second visit was conducted with the office staff, in particular the office manager or the person who ordered the vaccine and was responsible for vaccines, not the physician. Only those offices that had participated in Phase I were visited in Phase II.

3.8 Data Analysis

The data from the questionnaire were analyzed using EPI-INFO; version 6, (1994) for frequencies and proportions to provide a description of the study population. Comments and discussion of common themes and topics were analyzed by coding responses into categories, for example, the reason for obtaining a thermometer or comments on the present system for distribution.

Content analysis of the open-ended questions and comments were used to identify recurrent themes. Comments and topics from discussions were grouped and are also compared in relation to vaccine care. Cross tabulations were conducted with the data for comparison of setting (urban or rural (outside the municipal boundaries of St. John's/Mount Pearl)), number of years in practice, whether an office was group or solo. A group practice is one with two to six physicians sharing an office and the same storage facilities for the vaccine. All of the physicians in a group used the vaccine that was stored in the same office refrigerator. A solo practice is one where the physician works alone). The final demographic information collected was the gender of the physician (or the physician who immunized in that office) completing the questionnaire.

CHAPTER 4

RESULTS

The results will be presented in five sections. First the characteristics of the study population will be reviewed for participation and demographics. This will be followed by findings from each of the areas assessed: a) Knowledge and Responsibility, b) Storage of Vaccine and c) Temperature and Documentation. As described in the methods section, these areas represent the national guidelines for storage and handling. Finally there will be a section on temperature and a summary of guideline compliance.

4.1 Participation

The populations available are those physicians who provide childhood immunization on the Avalon Peninsula. This study represents the majority of physicians who provide childhood immunizations in the province of Newfoundland and Labrador. The participation rate of the study was 73% (27/37) offices and 75% (67/ 89) of all the physicians who provide childhood immunizations on the Avalon Peninsula. Tables 4.1 and 4.2 provide an overview of the participation by the number of offices, number of physicians, practice type, and geographic location.

Table 4.1 Participation by Number of Offices and by Practice Type and Location

Type of practice	Rural (%) n=13	Urban (%) n=24	Total (%) n=37
Solo	6 (46%)	2 (8%)	8 (22%)
Group	6 (46%)	13 (54%)	19 (51%)
Total participating	12 (92%)	15 (63%)	27 (73%)
Total refused	1 (8%)	9 (38%)	10 (27%)

n = number of offices

Table 4.2 Participation by Number of Physicians and by Practice Type and Location

Type of practice	Rural (%) n=30	Urban (%) n=59	Total (%) n=89
Solo	6 (20%)	3 (5%)	9 (10%)
Group	23 (77%)	35 (59%)	58 (65%)
Total participating	29 (97%)	38 (64%)	67 (75%)
Total refused	1 (3%)	21 (36%)	22 (25%)

n = number of physicians

Contacting the office and arranging the office interview took varying lengths of time. The number of calls to set up a visit ranged from two to six calls with the average four calls.

In the rural offices, an equal number (6) of solo and group practices was visited. The group practices in the rural areas represented 23 physicians and there were six solo practices, for a total of 29 (97%) of the available physicians captured. In the urban area the participation rate was lower at 64%. In St. John's, 35 of the physicians who participated were in group practices and 3 in solo practices. There were more than twice as many group practices compared to solo practices. Of the ten offices that refused to participate there were two solo and eight group practices. One (8%) rural office refused while 9 (38%) urban offices refused.

When a telephone call was made, it was left to the secretary to decide whether or not the request was brought to the physician. Two of the secretaries in the urban area responded: "I can check for you but Dr. — does not do that sort of thing". In these cases the physicians may have been approached, but participation was denied. This limitation was addressed with subsequent telephone calls and in some cases speaking with the physician; this resulted in one visit that had been denied previously. Solo practices in both urban and rural generally responded that it was impossible to participate, as he/she was the only person in the clinic. The most common reason given for not participating - "the office is too busy" - came from four of the ten offices (40%); two stated that they did not participate in surveys and the remaining four did not give a reason for their non-

participation.

4.2 Demographics

In this section information was collected on sex, the number of years in practice and number of immunizations given in the average week by the physicians in that practice. In each practice one person was responsible for vaccine care; this person completed the interview. In two offices the person responsible was an office manager, and in the remaining 25 offices it was a physician. The office managers provided information for the physicians who gave the most childhood immunizations in that office.

Table 4.3 Demographic Features of Physicians Responsible for Vaccines and Number of Vaccines Administered in a Week

		Rural (%)	Urban (%)	Total (%)
		n=12	n=15	N=27
Sex	Male	9 (75%)	6 (40%)	15 (56%)
	Female	3 (25%)	9 (60%)	(44%)
Years in Practice				
	<1	0	0	0
	1-9	2 (17%)	4 (27%)	6 (22%)
	10-19	6 (50%)	8 (53%)	14 (52%)
	20-29	4 (33%)	3 (20%)	7 (26%)
Average number of vaccines given in a week per physician on average in a practice				
	1-4	6 (50%)	7 (47%)	13 (48%)
	5-9	2 (17%)	4 (27%)	6 (2%)
	10-14	2 (17%)	3 (20%)	5 (19%)
	>15	2 (17%)	1 (7%)	3 (11%)

Of all the physicians' males and females were almost equally represented, 12 (44%) females and 15 (55%) males. All participants had more than one year of experience, with the majority having greater than ten years experience (78%). Twenty - two percent of the physicians interviewed had one to nine years' experience.

The physician or office manager who was interviewed was asked how many immunizations were provided, on average, in a week. The number of immunizations

carried out by physicians in a week was relatively low with almost half (48%) providing from one to four immunizations in the average week. All of the solo practices, regardless of urban or rural, performed only one to four immunizations a week. Two of the solo offices reported that they provided only ten immunizations a year. Twenty-two percent gave five to nine immunizations a week, 19% ten to fourteen and only 3 group offices (11%) gave 15 or more a week.

4.3 Storage and Handling Practices, Phase I

Tables 4.4 through to 4.8 provide an overview of the National Advisory Committee Guideline recommendations and demonstrate how actual practices compared with the ideal. For example, in regard to the guideline that one person is responsible for vaccine care, 25 of the offices had designated such a person. These tables are structured to the divisions of knowledge and responsibility, storage and temperature and documentation.

Table 4.4 Results of Knowledge and Responsibility Questions

Guideline	Practice met guideline (%) n=27
One person in the practice should be responsible for vaccines	25 (93%)
All persons responsible for handling vaccines should be trained And know proper vaccine care	21 (78%)
Power failure procedure should be posted on the door, and This should be followed in such an event	2 (7%)
Educational material should be available on the cold chain In all centres where vaccine is stored	27 (100%)
Procedures for “exposed” vaccine should be in place	25 (93%)
Refrigerators repaired as required	27 (100%)
Vaccine Associated Adverse Event forms should be completed	N/A

Twenty-five of the 27 (93%) offices had a designated person responsible for vaccine care. Not all persons were aware of the correct refrigerator temperature. When provided with three temperature options only 21 of the 27 (78%) chose the correct option, 2°- 8° C. Two offices (7%) had power failure procedures in place, two others had them but they were not posted. Similarly, no procedures for handling “exposed” vaccine were observed but 25 (93%) offices reported that they had them in place. All offices had educational material of some type on hand, including the *Canadian Immunization Guide* (in three offices this was an old edition), newsletter information from the Department of Health or the Health and Community Services office. All offices

responded that they were content with the system for distribution of vaccines and knew whom to call if problems arose. One frequent comment was that the form used to report immunizations to the Health and Community Services offices was “cumbersome”.

When the investigator questioned the physician about the Vaccine Associated Adverse Events form (see Appendix I) the response was that they had not required one as adverse events were infrequent. If they did have opportunity to report an adverse event, this would be by a telephone call to the local Medical Officer of Health in the Health and Community Services office.

Table 4.5: Results of Storage of Vaccine Questions and Observations

Guideline	Practice met guideline n=27 (%)
Vaccine should be stored in the main part (body) of the refrigerator, never on the door	27 (100%)
Vaccines should be refrigerated as soon as possible after transport	27 (100%)
Refrigerator should be dedicated to vaccine storage only	26 (96%)
Freezer available	3 (11%)
Defrost if more than one centimeter of ice has accumulated	3 of 3 with freezers
Vaccines should remain refrigerated except when in use	27 (100%)
Space should be left between vaccines to allow circulation of air	25 (93%)
Keep a sign near the electrical plug to prevent accidental loss of power	0 (0%)
Make sure the door is closed when not in use	27 (100%)
Adsorbed vaccines should be stored well away from ice or possibility of freezing	26 (96%)
Vaccine should be transported in insulated containers with appropriate freezer packs	4 (15%)
Water bottles should be used as a temperature stabilizer in the refrigerator	1 (4%)

Many of the vaccine storage issues were observed while the storage space was being assessed and the temperature of the refrigerator taken. In all practices vaccine was

stored in the refrigerator. The refrigerator door was not used for storage, and air was allowed to circulate around the vaccines. When asked about the procedure enforced upon receipt of vaccines, each office stated that the vaccines were immediately refrigerated. Only three of the practices had refrigerators with freezers. While this is not a guideline, it was assessed in the interest of future products, particularly varicella vaccine, which must be maintained at -20° C. Of the other 24 offices, one had a full-size, one-door model refrigerator which had the freezer compartment removed (because it was not used). Of these 24, 23 had half-size refrigerators without a freezer compartment. Only one office had water bottles at the top, bottom and sides to act as a temperature stabilizer in the event of a power loss. This item was the most commonly deficient.

Vaccine was transported in a thermal bag or in a cooler in four rural practices (15%). Those offices within a five-to ten-minute drive felt that a paper bag was sufficient to maintain the 2°- 8° C and the offices stated that that was how the regional depot had provided the vaccine.

Table 4.6 Results of Temperature and Documentation Questions and Observations

Guideline	Practice met guideline n=27 (%)
All refrigerators should have a maximum-minimum Thermometer	10 (37%)
Two daily readings of the refrigerator temperature should be taken and recorded	1 (4%)
The temperature of the storage refrigerator should be between 2° - 8 °C	24 (89%)
Immunization should be recorded on the patient's chart	27 (100%)
Immunization should be recorded and given to the patient or parent	26 (96%)
A record of immunization should be forwarded to the Health and Community Services office	25 (93%)

While ten of the offices had thermometers, only eight documented the temperature of the refrigerator where vaccines are stored on a regular basis. None of the practices documented the temperature of the refrigerator on a twice-daily basis, as per the recommendations.

The recording of immunization includes: Vaccine type, lot number, dosage, site where the vaccine is given, the date administered and a record of

immunization given to the individual who has been immunized. All of the offices questioned responded that they recorded immunization information on the chart, and all but one office gave a record to the patient and all but two forwarded a record to the local Health and Community Services office.

Table 4.7 Temperatures in Refrigerators

Temperature in degrees Centigrade	No. of practices (%)
0	1 (4%)
4	3 (11%)
5	5 (19%)
6	8 (30%)
7	6 (22%)
8	2 (7%)
9	2 (7%)

n = 27

The correct temperature of the refrigerator where vaccine was stored, between 2°- 8° C, was recorded in 89% of the physicians' offices. In two of the urban and one of the rural physicians' offices, the temperatures were outside the range of 2°- 8° C.

Table 4.8 Number of practices and location by number of guidelines met

Number of guidelines (%) met of 24 Questioned or observed	Urban n=14	Rural n=13	Total n=27 (%)
24 (100%)	-	1	1 (3.7 %)
23 (96%)	1	-	1 (3.7%)
22 (92%)	-	2	2 (7%)
21 (88%)	4	4	8 (29.6%)
20 (83%)	1	6	7 (25.9%)
19 (79%)	7	-	7 (25.9%)
18 (75%)	1	-	1 (3.7%)

In summary, only one office met all of the 24 guidelines, one met 23 of the 24 and 2 met 22 of the 24. The majority (81%) of the offices met between 19 to 21 (79-83%) of the 24 guidelines. The guidelines that were most commonly

deficient in Phase I included:

- The power failure procedure was not posted on the door in 22 of the 27 offices, (92% were deficient in the initial visit).
- The vaccines were not transported in insulated containers with appropriate freezer packs in only 23 of the 27 offices, (85% were deficient in the initial visit).
- Water bottles were not used as a temperature stabilizer in the refrigerator in 26 of the 27 offices, (96% were deficient in the initial visit).
- Maximum-minimum thermometers were not used in 17 of the 27 refrigerators, (63% were deficient in the initial visit).
- Two daily readings of the refrigerator temperature were not taken in 26 of the 27 offices, (96% were deficient in the initial visit).

4.4 Results of Phase II

Phase two of the project was completed four to eight months after the initial visit. The 27 offices that had participated in Phase I of the study were the focus of Phase II. These offices were visited unannounced and the storage and handling practices again assessed, with a specific focus on the areas found to be deficient in the initial visit.

The offices that used thermometers as well as had the proper storage and handling procedures in the initial visit still had the same procedures in place in the Phase II visit. The most notable change that had occurred after the initial visit and intervention was that eight of the 17 offices, which did not have a thermometer in the initial visit, had obtained one by the second visit. Two more (for a total of three) of the offices had started using water bottles and one additional office had started documenting the refrigerator temperature on a weekly basis. The documentation sheet was observed and the temperature had remained between the 2° C - 8°C range. These results are summarized in Table 4.9.

Table 4.9 Summary of Results of Phase II, Post Intervention

Guideline found to be deficient	Number meeting guideline in Phase I n=27	Number initiating guideline post intervention n=27	Total number meeting guidelines at the end of Phase II n=27
Thermometer	10	8	18
Temperature documented	1	0*	1
Water Bottles	1	3	4

Note * 4 offices had begun to document on a weekly basis but no offices documented twice a day

4.5 Summary

In summary, the results indicate that physicians on the Avalon Peninsula are meeting many of the guidelines that are applicable to physician practices. The modifications that were most frequently recommended at the end of the first visit included obtaining a thermometer, using water bottles, and monitoring refrigerator temperatures. The intervention, providing information on proper storage and handling including ways to implement those measures that were lacking, was well received by those responsible for vaccine care. The second unannounced visit indicated little change in the practice. The second visit also verified the findings of the initial visit, in that the

methods in place were ongoing and not merely there for the purpose of the visit.

CHAPTER 5

DISCUSSION

This discussion of the results will indicate the relationship of the results to the objectives of the research and the hypothesis. The results will be compared to similar studies from the literature that has assessed vaccine storage and handling in the United States, the United Kingdom and other provinces in Canada. The results are also compared with a review of the national guidelines to indicate how comparable the actual practice is to the national guidelines. A summary of the limitations of this study is also included.

The hypothesis that physicians' practices do not meet the national guidelines for storage and handling of vaccines was not supported by the findings of this study. Physicians' offices did meet the majority of the guidelines as evidenced by the results. Recommendations for change resulting from an identification of the deficiencies will be expanded upon in the discussion.

The hypothesis that an intervention would improve practice was supported as evidenced by the improvement observed at the second visit.

5.1 Participation Rates

Historically, physician participation in surveys is low (Studnicki et al., 1993; Goethe et al., 1997). In an October 1998 survey request to physicians in Newfoundland

and Labrador for response to a memorandum of understanding regarding fee-for-service and salary levels, a 55% response was considered excellent with the normal response rate between 30-35% (L. Collins, personal communication, March, 1998). The participation rate is comparable to other cold chain studies in the United Kingdom (Bishai et al., 1992; Thakker & Woods, 1992; Briggs & Illett, 1993). With 92% of rural practices (12/13) and 62% (15/24) of the urban practices participating, the participation rate of 73% is very good compared to the other studies, but there is an element of personal contact which has influenced the participation.

In the urban setting, physicians had a participation rate of 64% (38/59) lower than the 97% (29/30) of rural physicians (see Table 4.2). Several local events at the time of the study may have impacted on the participation from both urban and rural areas. Easter school break fell during this period and physicians' offices are typically busier during holidays. Several offices had staff on annual leave. There was an outbreak of salmonellosis in school age children in early April 1998, which may have increased physician workload, and there were higher than normal rates of parvovirus reported on the Avalon Peninsula during April and May. All of these factors may have affected the participation rate. Salary negotiations between the Department of Health and Community Services and the Newfoundland and Labrador Medical Association had also reached a difficult period (Gushue, J., April, 1998). No studies, which compared participation rate differences between rural and urban physician practices, were found.

Participation rates did not vary by practice type, the same percentage of refusals

came from both settings. In rural practice there were eight solo and six group practices available; one solo (8%) practice refused a visit. In the less populated areas of rural Newfoundland, there tends to be more solo than group practices (L. Collins, personal communication, March, 1998). The more populated areas of St. John's and environs had only five solos and 19 group practices available; refusals came from two of the five solo practices (40%) and seven of the 19 (37%) group practices.

If an office was uncertain about participation when first contacted, as many as eight to ten telephone calls were made over the three month period of April, May and June, 1998. These offices were contacted again in September and October through an average of three to four telephone calls and again a request to visit was denied. While full participation was preferable, after 11-15 requests, further contact was not made. The research protocol had limited the number of attempted telephone calls to 15.

One of the concerns prior to the study was that physicians would feel threatened and therefore choose not to participate. It is impossible to state whether or not the offices that refused did so as a result of feeling threatened. When the visits were completed, there were some comments from staff and physicians indicated that the visits were welcome:

"It is great to have someone come to the office and check on what we are doing with vaccines".

"Childhood immunization has always been a very positive aspect of my practice and lends to the true meaning of family practice, seeing

people when they are well”.

5.2 Characteristics of the Sample

From the demographic information available (telephone listing for the number in a practice and the Newfoundland Medical Board for number of years in practice) the characteristics of the groups in urban areas who refused did not significantly differ from those who participated. They were all in practice for over one year, had practices throughout the same geographical area and the practices were a mixture of male and female physicians.

In all 27 visits the person chosen from the group practice to respond to the survey was the individual responsible for immunization. If the office manager responded he/she did so on behalf of the physician who was designated to be responsible for vaccine storage and handling. This method of response provided demographic information for a physician in all 27 offices. Twelve female and 15 male physicians completed the survey. The sex of the physician, geographic location of the office and the number of years in practice were similar for all participants, close to half female (45%) or male (55%). Refusals came from two solo practices in each of rural and St. John's, both of these were male physicians. Of the seven refusals from urban group practices three were males only and three were females only and one group was mixed male and female. While this is interesting, the small sample size does not allow for analysis of a statistical relationship

between urban and rural offices.

Most (78%) of the physicians who participated had been in practice for ten or more years. No physicians interviewed had less than one year of experience. The storage and handling practice of vaccines was not related to years of physician experience.

On average the physicians give one to four childhood immunizations a week. This was lower than the number provided by public health nurses who provided five to nine every week (O'Keefe, 1997). One rural physician stated that he provides fewer childhood immunizations in the late 1990s, but may have a patient who cannot attend the public health clinic because they are not offered in the evenings.

It is worthwhile to note that all (9) of the solo practices, from urban and rural areas, provide less than one to four vaccines in a week (two or five a month). The doctors in the solo practices explained that the ages of their patients do not warrant childhood immunizations. The group practices performed more immunizations per physician, on average five to 20 a week.

The survey and visit provided information from 73% of all physicians who provide childhood immunizations on the Avalon Peninsula of Newfoundland and Labrador. Fewer refusals came from the rural area; solo practices tended to give fewer immunizations a week and no association was noted between immunization practice and the number of years in practice. As these physicians continue to provide childhood immunizations the primary research question becomes more relevant: are the vaccines stored properly and do they provide as effective a product as possible?

5.3 Guideline Assessment

Twenty-four of the 35 storage and handling guidelines were evaluated in this study. The recommendations, which are appropriate in a physician's office, were assessed and data collected on how closely the guidelines were followed. This study did not assess those recommendations dealing with policy and vaccine programs, which are the responsibility of the province.

Solo practices (8) consistently met only 18 and 19 of the 24 guidelines observed. Although one solo office that provided about five vaccines a week met 21/24 of the guidelines, the remaining seven provided less than four vaccines a week and met less than 20/24 of the guidelines. Group practices (19) met 21 of the 24 guidelines or greater, but only one practice met all 24 guidelines.

5.3-1 Knowledge and Responsibility

According to the guidelines, 93% of practices had one person responsible for the care of vaccines. In 78% of the practices the person who was responsible for vaccine care also knew the correct storage temperature. In each practice, the person assigned to vaccine care varied, with office managers carrying the responsibility in most (89%) cases and the other 11% were the physicians themselves. The lack of an individual assigned with this responsibility was a significant problem in the United Kingdom (Thakker & Woods, 1992; Hunter, 1989). Having only one person responsible for vaccine care

provided consistency and follow-up. This person would typically place the orders, check the stock for expired vaccine, check for adequate space between the boxes to allow airflow and maintain the thermometer and document temperature. Vaccine orders were filled on a monthly basis, thereby eliminating the need to stockpile vaccines. The same person was responsible in Phase II, with one exception, when a maternity replacement was also the office manager. The two offices without someone responsible for vaccine care were groups from the urban setting. Of the six who did not know the correct temperature two were solo, one each from rural and urban, and the remaining four were group practices in St. John's. The non-physician office managers who responded did not differ from the physicians.

The person from each of the participating practices responsible for vaccines responded accurately to many of the questions regarding the care of vaccines. When asked the correct storage temperature, some physicians quickly stated "refrigerated". When asked to choose from three options, 78% gave a correct response. To the choices of i) 5°-10° C ii) 0° - 3° C iii) 2° - 8°C, iii is the correct response. In conversation, the individuals who are responsible for vaccine care replied that they had received information regarding vaccine care from varied sources including peer review, newsletters and letters from the Health and Community Services offices.

When asked if the office held educational materials on vaccine care all 27 responded yes, but the investigator did not observe these materials. With regard to the *Canadian Immunization Guide*, three (11%) of the offices were using the older 1991

edition. The physicians with the old copies saw “no need” to purchase a new edition. Eight (30%) offices indicated that they did not have a guide and five (19%) others had an “old copy somewhere” but did not see a need to buy the *Canadian Immunization Guide*. The remaining 14 (52%) offices did not know if they had a copy of the guide. In late 1998 the new edition of the *Canadian Immunization Guide* (5th ed.) was made available to all physicians in Canada. In Phase II all offices had the current copy and the publication was also available online. This edition provides a complete section on storage and handling of vaccines. While all offices had a copy, no major changes in practice had occurred. The simple provision of the guide did not achieve a behavioral change. This had been reflected in the literature (Arif et al., 1998).

Sixty-three percent (17/27) of those interviewed were not familiar with the specific Vaccine Associated Adverse Event form (see Appendix I). The other ten offices had heard of the form but had no need to use it. Discussion that flowed from this question demonstrated that very few (less than one or two a year) had any “adverse events” to report. Mild (expected fever, sore arm or thigh) adverse event reports were not sought but would arise prior to the next immunization. No offices reported an active surveillance for adverse events. Physicians commented that there were “even fewer” events since the introduction of the acellular pertussis vaccine in 1997. Those physicians who had occasion to report an adverse event did so with a telephone call to the local Health and Community Services office.

Of the available 27 participating offices only four (15%) had a concern about the

present process of vaccine distribution. The same complaint came from all of these four offices – two rural and two urban. This concern involved the method of documenting, recording and forwarding this information to the Health and Community Services office. According to one of the physician's interviewed this task was "too cumbersome, time consuming and required copies sent after each immunization". He commented that this inefficient method should be changed.

5.3-2 Storage of Vaccines

All offices (27/27) were equipped with refrigerators and stored vaccines on the center shelves of the main section of the refrigerator. This was not the expected outcome as the literature had overwhelmingly found that vaccine was not stored in a refrigerator and if a refrigerator was used often vaccine was placed in the door (Daniels et al.; 1991, Haworth et al., 1993; Steinmetz et al., 1983). Most commonly (81%) half size or "bar" refrigerators were used.

With regard to the guideline recommending storage of "vaccine only" in the refrigerator, the majority (96%) of practices did store only vaccines in the refrigerator. In Phase I, it was observed that one of the refrigerators was used to store blood samples and in Phase II, of the offices observed three stored blood in the vaccine refrigerator. It was confirmed that this was common practice. Those practices, which stored blood samples in the refrigerator designated for vaccines, were all in the urban area (one solo and two group practices). The office did not recognize that this was a problem. In one practice, the full-size refrigerator was shared with dentists who stored their lunches

there. The office manager stated that this could not be avoided.

It is recommended that water bottles be used to maintain the temperature of the refrigerator interior in the event of a power loss. None of the practices under study were aware of this recommendation. The data collected in Phase I indicated that only one (1/27) practice (a group rural practice) used water bottles; while Phase II showed a total of three (3/27) with water bottles correctly placed in two rural group and one urban solo practice. This, linked with the lack of power failure procedures – only one office had such a procedure posted – could lead to excessive wastage in the event of a power failure. The other practices “did not see any need” (4/27) or “knew what to do” (10/27) in the event of an extended power outage, the remaining ten had no comment. The participants also noted that they kept very little stock on hand; this helped to avoid wastage.

Vaccine was transported in a thermal carrier bag or cooler in four of the 27 (15%) offices. In rural areas where a courier is used and travel distances are longer, thermal bags or coolers were used. In all other cases (85%), the vaccine was picked up by a secretary, courier or physician and transported to the clinic refrigerator in 10 to 15 minutes. The Health and Community Services offices provide the vaccine in a paper bag. There are no studies available regarding the insulation value of a paper bag and the guidelines clearly state that a thermal carrier should be used. These findings were similar to United Kingdom studies that did not quantify the results but reported the problem of lack of refrigeration during transport as a problem (Briggs & Illett, 1993; Cheriyan,

1993; Haworth et al., 1993). In an Ontario study less than 22% of physicians reported the use of insulated containers for transport (Daniels & Naus, 1994). In Newfoundland no change was observed in the use of insulated carriers during the second visit of Phase II.

All 27 physicians' offices had 18 or more of the 24 guidelines for storage and handling practices in place. This was contrary to many of the studies that had been discussed in the literature from the early 1990s. Of specific note is a more recent study from Finn & Crook (1999) which showed significant improvement over those conducted by Hunter (1989), Haworth et al. (1993) and Thakker and Woods (1992). Physicians in the Finn & Crook study, much like those in this study, had started to use refrigerators for storage and physicians have shown gradual improvement toward maintaining the cold chain.

5.3-3 Temperature and Documentation

The use of thermometers in the vaccine refrigerators was higher than expected and was the most significant of the changes in methods from Phase I to Phase II. The literature review had indicated that few, if any, offices had thermometers (Daniels et al., 1991; Hunter, 1989; Thakker & Woods, 1992). In Phase I, 10 of the 27 offices (37%) had thermometers, and an additional eight had purchased and were using thermometers in Phase II. These offices with thermometers had found it difficult to find a thermometer in the early to mid-1990s and often the expense was considerable, ranging from \$30 to

\$150. The offices with thermometers in Phase I included one (1/6) solo rural practice, four (4/6) group rural practices and five (5/13) group urban practices for a total of 10 of the available 27 (37%) offices with thermometers. Those who purchased thermometers after Phase I had done so as a result of the study.

In the rural setting two solo practices had obtained a thermometer by the second visit, which made a total of three (3/6) solo rural with thermometers and three without thermometers. The three rural group practices who did not have a thermometer in Phase I had acquired one by Phase II. In the urban area, one solo (1/2) and two (2/13) group practices purchased thermometers, making a total of seven (7/13) group practices with thermometers. Further, the offices that purchased thermometers post-intervention found them more accessible in 1998 and at considerably lower cost of \$20 to \$50.

The temperature of the storage area was correct in 90% of the offices. Only one of the offices (rural group) documented the temperature on a regular basis (weekly or biweekly). Much discussion between the investigator and the person interviewed ensued on this topic. Most physicians (25/27) regarded the twice-daily documentation of refrigerator temperature as onerous. Two of the practices (one each urban and rural group) had implemented a daily record when the thermometers were first purchased. After a month or so it was found that the temperature remained constant; the practices felt that there was no longer any need to record this every day. Others (20/27) said they observed the temperature daily, but did not document it. This was also the experience in the United Kingdom, Canada and Australia (Hunter, 1989; Daniels & Naus, 1994; Finn

& Crook, 1999). Hunter indicated that only three of 36(8%) offices had thermometers in the refrigerator; this study did not enquire about documentation. In the study done by Finn and Crook, 27 of the 75 (36%) offices reported having a thermometer; 55% of these read the thermometer once a day and one-third recorded the temperature. Daniels and Naus (1994) reported that less than 15% of surveyed physicians used thermometers.

In this study, the one practice where the temperature was documented twice a week, the physician explained that an event a few years previously had prompted the change from non-compliance of the guidelines to compliance. In discussing this personal experience the physician related how the refrigerator had failed over a weekend and hundreds of dollars of vaccine had been wasted because the temperature was not known. This same office had a procedure posted that recommended specific action in the case of a power failure. Documenting the temperature had also been a recommendation of peer review and once physicians or the secretaries had started to do so it was "just part of the routine". The importance of documenting the refrigerator temperature was discussed during the first visit of this study, but only one additional office (rural) had begun to document temperature when the office was visited for Phase II. Physicians and office managers who responded to the questionnaire stated that documenting the refrigerator temperature twice a day seemed to be a waste of time. One practice had started documenting the refrigerator temperature daily but the temperature was the same every day for a month; so then they gave up the practice.

All offices (27/27) documented immunization on the client's chart and all but one

(26/27) provided the client with a record of his/her immunization. One urban solo practice physician did not provide a record; he gave the records to the Health and Community Services office and it was up to them to provide the record to the patient. When the importance of providing a record to the parent was discussed, the physician stated that he would take this into consideration. No change was noted in this practice in Phase II.

5.4 Availability of Freezers

The availability of freezers was not a practice guideline but was added as a matter of interest. Discussion at the 1996 National Immunization Conference, held in Toronto, included a new varicella vaccine which had to be maintained at -15°C . The introduction of this vaccine would partially depend upon the availability of freezers. Freezers were only available in three of the 27 (11%) offices surveyed. In two additional practices a full-size refrigerator was used but the freezers had been removed because they were not needed. All childhood vaccines in the 1999 schedule are best maintained at $2^{\circ}\text{--}8^{\circ}\text{C}$; therefore the refrigerator is acceptable without a freezer. A lack of freezers in physicians' offices could have implications for the distribution of the varicella vaccine if it was recommended as a universal childhood vaccine. Other studies did not reference collecting this type of information.

5.5 Impact of Peer Review

While peer review was not an initial part of this study, it became a recurring reason for the impetus to obtaining a thermometer. A review of the literature had indicated that peer review is one method that promotes physician compliance (Grol et al., 1988). From conversations with the physicians in this study, it was found that five of the ten offices currently with thermometers (3 rural and 2 urban, all group practices) had purchased them as a result of peer review. Peer review had been perceived as a positive experience and the physicians who had participated stated that it was “valuable”. This had been the expected outcome of the peer review process (Cohen, 1991). In the *Newfoundland and Labrador Medical Association Communiqué* (spring 1999), the proper storage and handling of vaccine remains listed as a “deficiency which directly affects patient care” (p. 13). For this reason the assessment of vaccine storage and handling will continue to remain part of the peer review. The second unannounced visit that indicated very little change suggested that peer review is more effective in facilitating change than the type of intervention (written materials) used in this study.

5.6 Limitations of the Study

Throughout the period of this study, certain limitations may have been of concern. The most significant limitation is that a bias may have occurred as a result of

those who chose not to participate (27%). Those refusing to participate may not have met any of the storage and handling recommendations. The non-participants, ten offices in total, comprised 27% of the total available sample of 37 offices. The refusals did not differ by age, sex or geography of the participants; therefore, their practice could have been similar. There is no indication that those physicians who refused had participated in peer review. The letters of introduction, sent from the Medical Officers of Health prior to the initial telephone contact, had stated the focus of the visit. Offices, who may not have been maintaining proper storage and handling of vaccines, may have refused a visit for that reason, not the one given at the time of the request.

An additional limitation, which may bias the study, relates to the letter of introduction sent by the Medical Officers of Health. This letter, a requirement of the Human Investigations Committee, informed the offices of the proposed visit as well as the topic of study. It is not known if this was reflected in the high adherence to guidelines in those offices that participated. The fact that two different letters were sent by the Medical Officers of Health may be a limitation, they could have had differing impacts on participation. If the same letter had been sent the urban participation rate may have been higher.

The instrument used to assess and measure the practice in physicians' offices had been previously tested for validity by peer review in the pilot. The questionnaire used in the pilot study was refined to more accurately reflect the true situation in the office. The questionnaire was comparable to that used in the Ontario Ministry cold chain assessment

(see appendix D) which had been validated through peer review. A lack of similar studies prevented an opportunity to provide an adequate instrument, which had established validity and reliability. The second unannounced visit also validated the findings of the initial visit when the same practice was observed.

The limited time for each visit (15-30 minutes) could only provide a snapshot of the practice. While storage of the vaccines was observed at that time, it cannot be ascertained whether the vaccine was left out during the practice day. Three of the offices had reminders posted on the refrigerator: "DO NOT LEAVE VACCINE OUT OF FRIDGE". The interviewees denied that this had been a problem.

This study looked at childhood immunization as a separate entity from those universal immunization programs that include influenza and pneumococcal vaccines for the older person and those at high risk of complications. These programs are provided almost exclusively by physicians, particularly in the fall of the year. Proper storage and handling practices are necessary to maintain the cold chain for these vaccines. The examination of these vaccines was not an objective of the study.

Finally, the sample size was a limitation. While all physicians who provide childhood immunizations were included, the small numbers of participants have implications for developing statistical inference. This is one of the main reasons that the findings of this study can not be generalized to all of the physicians' offices in Newfoundland and Labrador. While worthwhile information has resulted from this study, the large number of refusals in the urban setting makes it impossible to generalize.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

The purpose of this study was to assess storage and handling practices of vaccines in physicians' offices. It has provided a baseline for storage and handling practices for those offices visited, compared them to the national guidelines, and suggested areas where improvement is required. The research has provided an overview of storage and handling practices in Newfoundland, which had not been previously available. Approaches to physician compliance were also recognized as a valuable and necessary part of any guidelines or recommendations. This final chapter provides a summary of the conclusions, recommendations and suggestions for further research.

6.1 Conclusions and Recommendations

The assessed practices met many of the guidelines, with all offices meeting at least 18 of the 24 national guidelines. Those guidelines which were most commonly deficient included the absence of a thermometer, documentation of the refrigerator temperature, proper procedure in the event of a power failure, and the use of water bottles as a temperature stabilizer. The intervention during the first visit informed the person responsible for vaccines of proper procedures and identified the deficiencies that existed in their office. The largest change in post-intervention practice was the addition of a thermometer in eight of the seventeen (47%) offices, which lacked thermometers on

the initial visit.

Noncompliance with guidelines in physicians' offices as an issue is documented in the literature and reinforced by anecdotal information. For those offices that adhered to the guidelines, the most common factor ensuring compliance was peer review. Continued support for peer review is warranted since it encourages compliance.

The recommendations, which may best address the shortfalls, would involve an ongoing education program which would provide support for immunization and for those physicians who participate. This may be achieved through the following recommendations:

- The peer review process should continue to assess the cold chain and provide support and background information for proper storage. A partnering of the Atlantic Peer review, the Newfoundland and Labrador Medical Association and the Health and Community Services provincial and regional offices could facilitate this.
- The Health and Community Services offices must continue to provide information on immunization, storage, handling and documentation, and new vaccines.
- The process of transport (using paper bags) from the Health and Community Services offices to the physicians' offices poses an obvious opportunity for a break in the cold chain and should be changed. This method of transporting vaccines could easily go undetected and impotent vaccines could be providing an opportunity for disease in susceptible children. Strict application of the policy requiring physicians or Health and Community Services to supply thermal bags for vaccine pick up is

recommended.

- The use of temperature monitors should be considered for vaccine transportation, specifically for areas where vaccine may be en route for an extended period of time (greater than 15 minutes). Thermometers could be provided (at cost) to physician's offices.
- The documentation of immunizations required by Health and Community offices provides the required information for the proper charting of the immunization experience. The form had been described as "cumbersome" and "not user friendly". The development of an updated, more user-friendly form or computerised immunization registry would benefit the consumer, the physician's office and the Health and Community Services office. While this does not apply to storage and handling it was a finding when immunization was discussed with the participants.
- Close tracking of vaccine utilization could assist in maintaining effective inventory control.

6.2 Further Research

Compared with other topics of health and of public interest, the storage of vaccines garners very little publicity. Not all provinces provide an audit process, which would address the accountability of this portion of the physician's practice.

Guideline nine (see Appendix B), which requires twice daily recording of the refrigerator temperature, was the one guideline frequently seen by health care providers

as “non-evidence-based”. As a result, physicians questioned the appropriateness of this guideline, saying it was “too onerous”, and contributed little to the maintenance of the cold chain. The same response had come from the Health and Community Services office when the pilot study had been completed in 1997; these offices now measure the temperature twice a week. The feasibility of reducing the frequency of the recording should be investigated.

6.3 Summary

Most of the objectives of the research were completely attained. A good participation rate (73%) for the completion of questionnaires and visits to physicians’ offices to observe vaccine storage practices. For all offices visited the intervention materials were discussed and left with the person interviewed. The second visit was conducted allowing for a comparison of the initial practice with the post intervention practice. The assessed practice was then compared with the national guidelines.

Providing effective immunization with potent vaccine will control disease in the children and adults of Newfoundland and Labrador. This is one aspect of health promotion and disease prevention that has been engaged in widely for decades. While immunization dates back for well over a century, the focus for disease prevention remains on providing effective and safe vaccines. Maintaining the cold chain promotes the use of potent and effective vaccines, which in turn supports the public health goal of achieving health for all through communicable disease control.

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Appendix A

History of Immunization in Newfoundland and Labrador

HISTORY OF VACCINE USAGE AND TESTING IN NEWFOUNDLAND

MEASLES/ MUMPS/ RUBELLA

Vaccine (Code Name)	Age given	Year started	Year changed
Measles- Live (Lirugen)	9 months	Feb 1966	Sept 1970
Measles - (Lirugen)	12 months	Sept 1970	Oct 1972
Rubella- (Meravax)	12 months	Sept 1971	Oct 1972
Rubella- (Meravax)*	Grade 5	Sept 1972	1981
MR	12 months	Oct 1972	Dec 1974
MMR (MMR)*	12 months	Dec 1974	Sept 1996
MMR 2nd-dose added	12 & 18 months	Sept 1996	

*Also offered to rubella negative women post partum.

DIPHTHERIA/ TETANUS/ POLIO/ PERTUSSIS/ Hib

Vaccine (Code)	Age given	Year Started	Year Changed
Diphtheria (Plain)	varied	approx 1940	approx. 1996
Tetanus (Plain)	varied	approx 1940	approx 1991
Pertussis (Plain)	< 7yrs.	approx 1945	ongoing
Polio, Salk - IPV	varied	approx 1955	ongoing
Polio, Sabin - OPV * Replaced Salk IPV from 1973 to August 1978	varied	1962	Aug 1978
Diphtheria Pertussis Tetanus & Polio (QUAD)	2,4,6,18mo 4-6 yrs	1960	1984
Td&P	Grade 9	1978	ongoing
DPT&P Adsorbed (DALE)	2,4,6,18mo 4-6 yrs	May 1984	September 1997
Hib conjugate PRP-D (CONHIB)	18 mos	June 1988	June 1992
Hib conjugated PRP-D (Act-Hib)	2,4,6,18mos	June 1992	July 1994 & after for those not receiving Penta
DPT&P/Hib (PENTAVALENT)	2,4,6,18mos	July 1994	September 1997
DT&Polio (GLEN) For those not receiving pertussis	2,4,6,18mo 4-6 yrs.	July 1996	ongoing
DaPT&P/Hib (acellular pertussis PENTACEL)	2,4,6,18 mos	September 1997	ongoing
DaPT&P (QUADRACEL)	4-6 years	September 1997	ongoing

**Tuberculin Skin Test: CUTI/ TINE /Mantoux
BCG vaccination**

PRODUCT	Target	Year Started	Year Changed
Tuberculin skin test (Cutitest)	Student nurses School program	1948 1951	1975 Sept 1975
BCG vaccination for those who were skin test negative.	Student nurses	1948	1975
	School program	1951	Sept 1975 (1979 in Labrador)
Tine Test	spot check schools, employment etc.	approx 1972	approx 1982
5 T.U. PPD Mantoux		approx 1982	ongoing
2 step PPD		1996	ongoing

PRENATAL TESTING (Recommended)

TYPE	Year Started	Year Changed	Outcome
Rubella HLI	1975	ongoing	All rubella negative offered vaccine post partum or as necessary
Hepatitis B	January 1994	ongoing	All infants of HbsAg positive moms offered HBV vaccine
HIV	January 1997	ongoing	

OTHER

VACCINE	Age	Date Started	Date Changed
Hepatitis B *	High Risk / Health Care Workers	1985	ongoing
Hepatitis B **	Grade 4	Sept 1995	ongoing

Hepatavax first used and changed to Recombivax in 1987

* Recombivax and Engerix

** Recombivax only

Appendix B

National Guidelines for Vaccine Storage and Handling

Canada Communicable Disease Report

Relevé des maladies transmissibles au Canada

Date of publication: 15 June 1995

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Protecting Vaccines from Freezing in Extremely Cold Environments	97
Effects of Freezing on DPT and DPT-IPV Vaccines, Adsorbed	101
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Lignes directrices nationales pour la conservation et le transport des vaccins	93
Protection des vaccins contre le gel dans des environnements extrêmement froids	97
Effets du gel sur les vaccins DPT et DPT-IPV adsorbés	101
Fèvre hémorragique à virus Ebola	103

NATIONAL GUIDELINES FOR VACCINE STORAGE AND TRANSPORTATION

Preamble

Maintaining vaccines at the appropriate temperature from the time they leave the manufacturer to the time of administration, i.e., maintenance of the cold chain, is a very important aspect of proper immunization delivery programs. Lack of adherence to the cold chain may result both in lack of vaccine effectiveness, undue vaccine injuries, and an increased rate of local reactions after vaccine administration. Damage can be done by exposure to heat or freezing of the vaccine depending on the nature of the product. Recent studies have highlighted major deficiencies in Canada with respect to the cold chain. The Childhood Immunization Division, Bureau of Communicable Disease Epidemiology, Laboratory Centre for Disease Control has, therefore, undertaken the initiative to develop national guidelines for vaccine storage and transportation, in collaboration with those persons listed in Appendix I. The documents listed at the end of this appendix were also used in formulating these guidelines. A workshop on the practical aspects of the cold chain was part of the National Immunization Conference 'Immunization in the 90's: Challenges and Solutions', held in Quebec City, 5-7 October, 1994. The participants at the workshop, over 60 in attendance, were encouraged to comment on the national guidelines.

This document is provided as a general guide for consideration. It is aimed at all health care providers, the manufacturers, the provincial and territorial health authorities, as well as health units and pharmacies. Because of the wide audience, readers may find it lacking in specific recommendations for their particular jurisdiction. Such specific instructions could be developed in the various jurisdictions, especially depending on the nature of the product used. Operational questions should be resolved by the jurisdictions in consultation with the manufacturer(s). The Childhood Immunization Division has committed itself to strengthening its support to the provinces and territories with respect to the cold chain and will be hiring a technical officer as part of its action plan on vaccine-preventable diseases of infants and children. Information about technical issues, training, and educational material related to the cold chain can be obtained by writing to the Childhood Immunization Division, Bureau of Communicable Disease Epidemiology, Laboratory Centre for Disease Control, Tunney's Pasture, Ottawa, Ontario, K1A 0L2, or calling 1-613-957-1340 or 1-800-363-6456.

LIGNES DIRECTRICES NATIONALES POUR LA CONSERVATION ET LE TRANSPORT DES VACCINS

Préambule

Le maintien des vaccins à la température appropriée à partir du moment où ils quittent les locaux du fabricant jusqu'au moment où ils sont administrés — c'est-à-dire le maintien de la chaîne du froid — constitue un élément primordial d'un programme de vaccination efficace. Toute rupture de la chaîne du froid peut entraîner une diminution de l'efficacité du vaccin, un échauffement et un taux accru d'effets secondaires. L'exposition à la chaleur ou au gel peut endommager les vaccins, selon la nature du produit. Des études récentes ont mis en lumière un certain nombre de problèmes importants en ce qui concerne la chaîne du froid. La Division de l'immunisation des enfants, Bureau de l'épidémiologie des maladies transmissibles, Laboratoire de lutte contre la maladie a donc pris l'initiative d'élaborer des lignes directrices nationales concernant la conservation et le transport des vaccins, en collaboration avec les personnes dont le nom figure à l'annexe I. Nous nous sommes également inspirés des documents énumérés à la fin de cette annexe en vue de la rédaction des présentes lignes directrices. Une conférence nationale sur l'immunisation, intitulée : «L'immunisation des années '90 : défis et solutions», qui a eu lieu à Québec, du 5 au 7 octobre 1994. Les quelque soixante personnes qui ont participé à cet atelier ont été encouragées à faire des commentaires sur les lignes directrices nationales.

Le présent document se veut un guide général pour votre usage s'adressant à tous les professionnels de la santé, aux fabricants, aux autorités sanitaires provinciales et territoriales de même qu'aux bureaux de santé et aux pharmacies. En raison de son vaste public, il ne peut contenir de recommandations spécifiques s'appliquant à leur situation. Des telles instructions spécifiques pourraient être élaborées par les divers intervenants, selon la nature du produit. Les questions opérationnelles devraient être résolues par les provinces et territoires en consultation avec les fabricants. La Division de l'immunisation des enfants s'est engagée à accroître son appui aux provinces et aux territoires en ce qui concerne la chaîne du froid et embauchera un agent technique cadre de son plan d'action pour lutter contre les maladies des nourrissons et des enfants qui peuvent être prévenues par la vaccination. Les personnes intéressées peuvent se procurer de l'information sur certains aspects techniques, de la formation ainsi que du matériel éducatif en écrivant à l'adresse suivante : Division de l'immunisation des enfants, Bureau de l'épidémiologie des maladies transmissibles, Laboratoire de lutte contre la maladie, Pré Tunney, Ottawa (Ontario) K1A 0L2 ou en téléphonant : 1-613-957-1340 ou au 1-800-363-6456.

General recommendations

1. Practices relating to the cold chain should be reviewed periodically at all levels (i.e., every 6 months to 1 year). Where excessive cold chain failures occur, reviews should be more frequent.
2. Vaccines exposed to temperatures outside those stated in the manufacturer's insert or labelling should be stored in a separate, marked container in a well-functioning monitored refrigerator until clear instructions have been received on what to do with them. Because the potency of different vaccines varies depending on the type of temperature exposure, each incident must be evaluated individually.
3. Records should be kept of doses received, including lot numbers for each vaccine shipment, and of wastage after vaccine expiry dates have passed.

Recommendations about storage

1. Vaccines should never be removed from the refrigerator except for the following reasons: withdrawing a dose(s); shipping to clients; or transporting to immunization clinics. The refrigerator door should not be opened too frequently. (The World Health Organization recommends that the door should not be opened more than four times a day).
2. Vaccines should be stored in the refrigerator as soon as they are received.
3. All persons responsible for handling vaccines should know the correct storage temperatures for the various vaccines.
4. A refrigerator dedicated only to vaccine storage should be identified and used only for this purpose. Vaccine refrigerators should not be used to store staff lunches or specimens.
5. If there is an accumulation of more than 1 cm (or 1/4 inch) of ice in the freezer compartment of a refrigerator, defrosting is required. Vaccines should be transferred to a vaccine carrier box or another refrigerator while this is being done. The temperature should be monitored during this contingency period.
6. One person should be identified as responsible for vaccine management. Another individual should also be trained for when the first person is absent.
7. All vaccine storage refrigerators should have a maximum-minimum thermometer or, if large quantities of vaccines are stored, a continuous temperature recording device. All monitoring devices should be certified or calibrated routinely.
8. All refrigerators containing large quantities of vaccine (e.g., central vaccine distributing areas) should also be connected to a temperature alarm monitoring system.
9. Two daily temperature readings for the vaccine refrigerator should be taken and recorded — one in the morning when arriving and one at the end of the day — to ensure temperatures remain between 2°C and 8°C. A chart-recording thermometer should also be checked for temperature fluctuations, which may occur between readings. The designated staff person should record and sign off readings in a log book daily. The designated staff person should ensure that all staff handling vaccines know how to read and interpret maximum-minimum thermometers.
10. All staff handling vaccines should have training about the importance of good vaccine storage and transportation techniques.

once week

Recommendations générales

1. Les pratiques relatives à la chaîne du froid devraient être revues périodiquement à tous les niveaux (c'est-à-dire tous les 6 mois ou les ans). Dans les cas où les incidents (rupture de la chaîne du froid) sont très nombreux, cet intervalle devrait être plus court.
2. Les vaccins qui sont exposés à des températures inférieures ou supérieures à celles qui sont indiquées sur la notice ou l'étiquette du fabricant devraient être conservés dans un contenant distinct, clairement identifié, dans un réfrigérateur en bon état de marche et la température est surveillée, jusqu'à ce que des instructions claires aient été reçues concernant les mesures à suivre. Étant donné que l'efficacité de différents vaccins varie selon les températures auxquelles ils sont exposés, chaque incident doit être évalué individuellement.
3. Il y aurait lieu de tenir des registres des doses reçues, notamment : numéros de lots, pour chaque envoi de vaccins, ainsi que des pertes dues au fait que la date de péremption est passée.

Recommendations relatives à la conservation

1. Il ne faudrait jamais retirer les vaccins du réfrigérateur, sauf pour raisons suivantes : utilisation d'une ou de plusieurs doses; expédition des clients ou transport aux cliniques de vaccination. Il faut ouvrir la porte du réfrigérateur le moins souvent possible. (L'Organisation mondiale de la Santé recommande de ne pas ouvrir la porte plus de quatre fois par jour).
2. Les vaccins devraient être placés au réfrigérateur dès leur réception.
3. Toutes les personnes qui sont appelées à manipuler des vaccins devraient connaître les températures de conservation recommandées pour les divers vaccins.
4. Il faudrait dédier un réfrigérateur à la conservation des vaccins et l'utiliser uniquement à cette fin. Ces réfrigérateurs ne devraient jamais être utilisés pour des aliments ou des spécimens.
5. S'il y a une accumulation de plus de 1 cm (1/4 de pouce) de givre le congélateur d'un réfrigérateur, il faut procéder au dégivrage. Il convient de placer les vaccins dans un contenant de transport ou dans un autre réfrigérateur pendant cette opération et de surveiller la température.
6. Il faudrait désigner un responsable de la gestion des vaccins. Il y aurait également lieu de former une seconde personne qui pourrait prendre le relais en cas d'absence du responsable.
7. Tous les réfrigérateurs utilisés pour la conservation des vaccins devraient être munis d'un thermomètre à maxima et minima ou, si de grandes quantités de vaccins sont conservées, d'un dispositif d'enregistrement continu de la température. Tous les appareils de surveillance devraient être homologués ou calibrés régulièrement.
8. Tous les réfrigérateurs contenant de grandes quantités de vaccins (exemple : dans les centres de distribution de vaccins) devraient également être reliés à un moniteur de température muni d'un dispositif d'alarme.
9. Il faudrait prendre deux lectures quotidiennes de la température du réfrigérateur à vaccins et consigner ces données — soit une lecture le matin à l'arrivée et une autre à la fin de la journée — afin de veiller à ce que la température se maintienne entre 2°C et 8°C. Il faudrait également vérifier les fluctuations de température, qui peuvent se produire entre deux lectures. À l'aide d'un thermomètre à enregistrement graphique. La personne désignée devrait noter les lectures d'instruments dans un registre chaque jour et apposer sa signature. Elle devrait également veiller à ce que toutes les personnes appelées à manipuler des vaccins sachent lire un thermomètre à maxima et minima et interpréter ces lectures.
10. Tous les membres du personnel qui sont appelés à manipuler des vaccins devraient recevoir une formation concernant les bonnes techniques de conservation et de transport des vaccins.

2. Central pharmacies and manufacturers who make long distance shipments should periodically use electronic monitors to detect possible problems and their location.
3. Shipping boxes for most vaccines should be clearly labelled as containing perishable goods that have to be stored between 2° C and 8° C and must not be frozen.
4. All transport companies carrying vaccines should be advised that the product is perishable and should be refrigerated immediately on receipt. Guarantees should be obtained that vaccines are kept in a refrigerated container from receipt to delivery.
5. Manufacturers should obtain written documentation from transport companies concerning the handling of perishable products (transportation, warehouse storage conditions, length of time between pick up and delivery, etc.). Refrigerated vehicles should be equipped with temperature monitoring devices.
6. If a vaccine shipment has been refused by the person who ordered it, the carrier must know that the shipment requires refrigeration pending resolution of the problem. The manufacturer or point of origin must be notified immediately for disposition of shipment.
7. All vaccines should be transported in an insulated container with an appropriate number of ice packs (except when shipped under refrigerated transit). Insulated containers should have firmly-fitting lids and be constructed from an insulated material. To avoid freezing, vaccines should not be placed directly on the ice pack.
8. Anybody responsible for the shipment of vaccine must ensure that the vaccine arrives at its point of delivery at the proper temperature.
9. Because ice packs removed from the freezer may be very cold, before they are used they should be left at room temperature for a few minutes (1 to 5 depending on the size of the ice pack and the initial temperature) until water or sweat appears on the surface to avoid freezing the vaccines.
10. If evidence of freezing is present when vaccines sensitive to freezing are received (e.g., results of temperature measurements), the vaccine must not be used.
11. Oral polio vaccine should preferably arrive with some dry ice still present. If this vaccine arrives with no ice remaining but with the product still cold, it may still be used; however, if the vaccine is warm, it should not be used.
12. Insulated carrier boxes should have documented ability (must be validated) to maintain the appropriate temperature for the anticipated maximum length of time required for the transportation.
13. When vaccines sensitive to freezing are to be shipped in outside temperatures of less than 2° C, they should be shipped in a vehicle in which the temperature should be kept higher than 2° C. If this is not possible and vaccines will be exposed to outside freezing temperatures, one should use ice packs with water at room temperature when packing the vaccine.
2. Les pharmacies centrales et les fabricants qui expédient des destinations éloignées devraient utiliser des moniteurs qui peuvent détecter des problèmes éventuels et l'endroit des produits.
3. Les boîtes utilisées pour expédier des vaccins doivent être inscrites indiquant qu'elles contiennent des produits devant être conservés à des températures entre 2° C et 8° C pas être congelés.
4. Il importe de bien informer les entreprises de transport des vaccins que ces produits sont périssables et qu'ils doivent être réfrigérés dès la réception. Il faudrait demander au transporteur que les vaccins seront conservés dans un conteneur à réception à la livraison.
5. Les fabricants devraient demander aux transporteurs des documents écrits indiquant comment sont manipulés les vaccins (transport, conditions d'entreposage, délai de ramassage et la livraison, etc.). Les véhicules réfrigérés doivent être équipés de moniteurs de température.
6. Si un envoi de vaccins est refusé par le destinataire, le savoir que le produit doit être réfrigéré jusqu'à ce qu'il soit réfrigéré. Il doit aviser immédiatement le fabricant ou l'expéditeur afin que celui-ci lui donne des instructions.
7. Tous les vaccins doivent être transportés dans un conteneur renfermant un nombre approprié de ice packs (sauf lorsqu'ils sont réfrigérés). Les contenants isolés doivent avoir un couvercle ajusté et être fabriqués d'un matériau isolant. Il ne faut pas placer directement les vaccins sur les ice packs, car ils pourraient geler.
8. La personne qui est responsable de l'expédition de vaccins doit s'assurer que ceux-ci arrivent à destination à la température appropriée.
9. Parce qu'ils sont très froids à la sortie du congélateur, les ice packs doivent être laissés à la température ambiante pendant quelques minutes (de 1 à 5 minutes, selon la grosseur de l'ice pack et la température initiale) jusqu'à ce qu'il apparaisse de la condensation sur la surface afin de prévenir le gel des vaccins.
10. Lorsqu'il y a lieu de croire que des vaccins sensibles au gel ont été exposés à des températures trop basses pendant le transport, par exemple, lorsque la température a été enregistrée pendant ces vaccins ne doivent pas être utilisés.
11. Un contenant renfermant des doses de vaccin oral doit encore contenir de la glace sèche au moment de la livraison. S'il n'y a plus de glace mais que le vaccin est encore froid, il peut être utilisé; cependant, si le vaccin est devenu chaud, il ne doit pas être utilisé.
12. Les contenants isolés qui sont utilisés pour le transport des vaccins doivent avoir la capacité éprouvée (validée) de maintenir la température appropriée pendant la période maximale prévue pour le transport.
13. Lorsque des vaccins sensibles au gel doivent être expédiés dans des températures extérieures inférieures à 2° C, ils doivent être transportés dans un véhicule dont la température est maintenue au-dessus de 2° C. Si cela n'est pas possible et que les vaccins sont exposés aux températures froides extérieures, il faut utiliser des ice packs contenant de l'eau à la température ambiante pour protéger les vaccins.

Appendix I List of collaborators

Mr. Peter Carrasco, Technical Officer for the Expanded Programme on Immunization, PAHO — WHO, Washington, D.C.

Annexe 1 Liste des collaborateurs

M. Peter Carrasco, Agent technique pour le Programme élargi de vaccination, Organisation panaméricaine de la santé, Washington, D.C.

Appendix C

Questionnaire used in Newfoundland

This questionnaire requests information on Immunization in your practice. The responses are confidential with no link between the response sheet to the office. The final report will discuss physicians as a group not individually.

Some questions about you and your practice:

1. Your sex:
☐Female ☐Male
2. How many years are you in practice:
☐ <1 ☐ 1-9 ☐ 10-19 ☐ 20-29
- 3a. Is your practice solo or group?
☐Solo ☐Group
- 3b. If group, how many physicians are in your practice?
☐ 1-3 ☐ 4-6 ☐ 7-9

Now some questions about immunization in your practice:

4. Do you provide childhood immunizations?
☐Yes ☐No
5. If yes, about how many do you give in a week:
☐ 1-4 ☐ 5-9 ☐ 10-14 ☐ >15
6. In your practice who is responsible for ordering vaccine?
☐Physician ☐Nurse
☐Secretary Other _____
7. Who is responsible for checking for expired vaccines?
☐Physician ☐Secretary
☐Nurse Other _____
8. Who picks up vaccine from the local depot?
☐Physician ☐Secretary ☐Nurse

- 9a. Is the vaccine transported in an thermal bag to your office?
☐Yes ☐No

- 9b. If no, in what type of container:

10. Where is vaccine stored in your office?

☐Door of fridge
☐Main part of fridge
Other _____

- 11a. Do you keep a thermometer in your refrigerator?

☐Yes ☐No

- 11b. If no, why not?

- 11c. If yes, does someone in your office record the temperature?

☐Daily ☐Weekly
☐Monthly ☐Not at all
☐Occasionally

12. How do you record immunization: (you may tick more than one response)

☐Written on chart
☐Written on a separate immunization record
☐Entered on a computer record
Other _____

13. Do you give a record of immunization to your patient (or parent)?

☐Yes ☐No
14a. Do you regularly submit a record of immunizations to the regional community health office?

☐Yes ☐No

14b. If yes, how often ?

14c. If no, why not ?

15a. Do you report Vaccine Associated Adverse Events?

☐Yes ☐No

15b. If yes what format do you use ?

15c. If yes, about how many in a year ?

Some questions on immunization in general:

16. Do you have a copy of the Canadian Immunization Guide ?

☐Yes ☐No

17. What is the optimum temperature for vaccine storage ?

☐ 5 -10° C ☐ 2-8 °C ☐ 0 -3° C

Some final questions on access to vaccines:

18. Does the current system for distribution of vaccines meet your needs ?

☐Yes ☐No

19. If no, how could it improve? _____

20. Would you like more information on the handling of vaccines ?

☐Yes ☐No

21. Would you like more information on different vaccines ?

☐Yes ☐No

22. Would you like to receive the result of this survey ?

☐Yes ☐No

Would you consent for me to measure the office Refrigerator Temperature

☐Consent ☐Refused

If consent, temperature: _____

Do you have any other comments:

Many thanks for you time and participation.

Appendix D

Questionnaire from Ontario Study



VACCINE UTILIZATION IN ONTARIO WHAT ARE YOUR PRACTICES?

The key person in your practice who is responsible for vaccine-related activities should complete questions 1 - 36 of this questionnaire. Questions 37-42 should be completed by the physician.

Please return to Stacy Daniels, Vaccine Utilization Review Project Coordinator, Disease Control Service, Public Health Branch by September 10, 1992. A stamped, self addressed envelope has been provided for this purpose.

Thank you for your participation in this study.

CIRCLE RESPONSE:

Organization of Vaccine Program

1. Is there a single person in the office who assumes primary responsibility for the care and storage of vaccines?

(a) Yes (b) No (c) Don't Know

If yes, is this person a ...

(a) MD (b) RN (c) RNA (d) Other

If other, specify: _____

2. Is there a written job description for the vaccine-related duties undertaken by this individual?

(a) Yes (b) No (c) Don't Know

If yes, attach copy

3. Who administers most vaccines in your office?

(a) MD (b) RN (c) RNA (d) Other

If other, specify: _____

Ordering of Vaccines

4. Are the majority of vaccines you order administered to children?

(a) Yes (b) No

If no, to whom? _____

5. On average, how often do you order and receive vaccines?

(a) Every Week (b) Every Two Weeks
(c) Every Month (e) Other

If other, specify: _____

6. From where do you order childhood vaccines?

(a) Local Public Health Department
(b) Ontario Government Pharmacy
(c) Hospital
(d) Other

If other, please specify _____

7. How do you decide what quantity of vaccine to order?

8. On average, how many doses of the following vaccines do you use each month?

DPT _____ doses
OPV _____ doses
Hib _____ doses
MMR _____ doses
Td _____ doses

9. Do you have a recording system in place to document all vaccines ordered and received?

(a) Yes (b) No (c) Don't Know

If yes, specify: _____

Handling and Transport of Vaccines

10. How do you receive your vaccines from the ordering source?

(a) Office Staff Pick-up (b) Courier Service
(c) Government Pharmacy Truck (d) Other

If other, specify: _____

11. During delivery to your office, are the majority of vaccines routinely transported with the following equipment?

Always Sometimes Never

Insulated Containers	1	2	3	4	5
Ice Packs	1	2	3	4	5
Paper Bags	1	2	3	4	5
Non-insulated Containers	1	2	3	4	5
Newspaper or Paper	1	2	3	4	5
Thermometers	1	2	3	4	5
Other	1	2	3	4	5

(Specify: _____)

12. Estimate the average time vaccines are left at room temperature:

Minutes Don't Know

a) during transport _____
b) upon arrival at office _____
c) during office use (e.g., between patients) _____

Storage of Vaccines

13. What is the age, type, and size of refrigerator used for vaccine storage in your office?

Age: _____ yrs.

Type: (a) laboratory
(b) kitchen
(c) other (specify): _____

Size: (a) full size
(b) half size
(c) other (specify): _____

14. Is the refrigerator used exclusively for vaccine storage or is it used for other purposes?

(a) Vaccines Only (b) Other Purposes

If other purposes, please indicate the other uses.

(a) Lab Specimens (b) Medications
(c) Staff Lunches (d) Other

If other, specify: _____

15. Is there a specific temperature, or range of temperatures, at which the refrigerator is maintained?

(a) Yes (b) No (c) Don't Know

If yes, please specify: _____ °C

16. Is there a thermometer for measuring the temperature in the refrigerator?

(a) Yes (b) No (c) Don't Know

If yes, how often do you read it in an average week?
_____ times.

17. Do you record temperatures in a log book or graph?

Always Sometimes Never
1 2 3 4 5

If always or sometimes, how often do you record them?

(a) Daily (b) Weekly
(c) Monthly (d) Other: _____

18. Have you had any refrigerator failures (freezing or warming) in the past two years that have resulted in vaccine loss?

(a) Yes (b) No (c) Don't Know

If yes, how many times? _____

19. Do you store new and old vaccine to facilitate using the older vaccine first (e.g., put in new vaccine on one side and take out from the other?)

Always Sometimes Never
1 2 3 4 5

20. Do you store any vaccines in the door of the refrigerator?

Always		Sometimes		Never
1	2	3	4	5

21. Is heat harmful to vaccines?

(a) All Vaccines (b) Some Vaccines (c) No Vaccines

If some, please specify which vaccine(s) are most sensitive to heat.

22. Is freezing harmful to vaccines?

(a) All Vaccines (b) Some Vaccines (c) No Vaccines

If some, please specify which vaccine(s) are most sensitive to freezing.

23. Do you know how to tell if DPT vaccine has been frozen, then thawed?

(a) Yes (b) No

If yes, how?

24. Is light harmful to vaccines?

a) all vaccines b) some vaccines c) no vaccines

If some, please specify which vaccine(s) are most sensitive to light.

25. Do you use multiple dose vials of some vaccines?

(a) Yes (b) No

If yes, what do you do with partially used vials of vaccine at the end of the office day?

(a) Keep (b) Discard

If keep, do you mark the date on the vials?

Always		Sometimes		Never
1	2	3	4	5

Do you put these vials in a special place?

Always		Sometimes		Never
1	2	3	4	5

How long do you keep them?

_____ days.

26. Do you store different vaccines separately (eg. one vaccine in one area of the refrigerator and another vaccine in a different area?)

Always		Sometimes		Never
1	2	3	4	5

27. Do you have office guidelines on proper storage and handling of vaccines?

(a) Yes (b) No (c) Don't Know

Vaccine Disposal

28. What is your policy about when to discard vaccines?

29. How do you dispose of vaccines?

(a) Return to Public Health Department
(b) Return to Government Pharmacy
(c) Return to Hospital
(d) Waste Basket
(e) Other (specify) _____

30. What proportion of all vaccines used in your office are discarded or returned for any reason?

_____ % of all doses

31. Which three of the following vaccines are most commonly discarded or returned?
(1 = most common)

☐ DPT
☐ OPV
☐ Hib
☐ MMR
☐ Other (specify) _____

32. Rank order the following reasons for vaccine loss from most common (1) to least common (5)

Temperature changes during transport _____
 Temperature changes during storage _____
 Temperature changes during handling _____
 Expired dates _____
 Other (specify) _____

33. What factors exist in your practice that increase the likelihood of vaccines being discarded?

34. Do you record discarded or returned vaccines?

Always 1 2 Sometimes 3 4 Never 5

If yes, where? _____

General Vaccine Practice

35. What information on immunization is routinely recorded on the patient's chart?

	Yes	No	Don't Know
Date	_____	_____	_____
Name of Vaccine	_____	_____	_____
Dose	_____	_____	_____
Route	_____	_____	_____
Site of injection	_____	_____	_____
Lot Number	_____	_____	_____
Manufacturer	_____	_____	_____
Signature	_____	_____	_____
Other info. (specify)	_____	_____	_____

36. What information on immunization is routinely recorded on the patient's own immunization record?

	Yes	No	Don't Know
Date	_____	_____	_____
Name of Vaccine	_____	_____	_____
Dose	_____	_____	_____
Route	_____	_____	_____
Lot Number	_____	_____	_____
Manufacturer	_____	_____	_____
Signature	_____	_____	_____
Other info. (specify)	_____	_____	_____

FOR PHYSICIANS ONLY

37. Where did you learn most about vaccine storage and handling?

(a) Medical School (b) Internship/Residency
 (c) Journals (d) Continuing Education
 (e) Ministry of Health Information (f) Product Information Sheets
 (g) Other (specify): _____

38. If you have any questions about vaccines (eg. immunization schedules, indications, etc.), who do you contact most often?

(a) Doctors in Similar Practices
 (b) Doctors in Speciality in Area
 (c) Other Nurses
 (d) Public Health Department
 (e) Ontario Government Pharmacy
 (f) Other (specify): _____

39. Do you review the invoice that arrives with your vaccines listing the actual costs of the vaccine?

Always 1 2 Sometimes 3 4 Never 5

40. Can you estimate the total dollar value of the publicly funded vaccines you have received over the last year?

(a) \$ _____ (b) Don't Know

41. Do you think physician's offices make a conscious effort to minimize vaccine wastage?

(a) Yes (b) No (c) Don't Know

Why or why not?

42. Do you have any comments or suggestions about how to improve the storage and handling of vaccines in Ontario? (Please use back for more comments)

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.

PLEASE USE THE SELF-ADDRESSED ENVELOPE PROVIDED AND RETURN!!

Appendix E

Informed Consent

Informed Consent for Participation in Immunization Practices in Physician Offices on the Avalon Peninsula

My name is Cathy O'Keefe and I am a graduate student of Memorial University of Newfoundland. My professional background has been in Public Health and Disease Control and Epidemiology. As part of my studies I am conducting research related to immunization practices. I have received approval from Memorial's Human Investigation Committee to conduct this study. I have also talked with representatives of the College of Family Physicians, the Newfoundland Medical Board, the Newfoundland and Labrador Medical Association, Community Health St. John's Region and Community Health Eastern who are aware of this study.

Purpose of Study:

- To assess present immunization practices in physicians offices with particular focus on storage handling and documentation.
- To provide information to support proper storage, handling and documentation in physician practice setting.
- To assess the change in the immunization process in physician practice setting from an initial to a second visit.
- To compare pre and post intervention practice with national guidelines.

Description of Procedure:

Today's interview will take about 10-15 minutes and with your permission will involve question: measuring the temperature of your refrigerator, and providing information on storage, handling and documentation. In three or four months I will drop back and discuss with you, or your secretary, the use of documentation materials and whether or not they are effective, measure the refrigerator temperature and collect any comments on immunization.

Confidentiality:

All of the information provided will be kept confidential. A code number will be placed on the interview form and these will be secured in a locked cabinet. The identification of physician practices to the code will be held by my thesis supervisor Dr. Bill Bavington, Memorial University.

Liability Statement:

Your signature indicates your consent and that you have understood the information regarding this research study. In no way does this waive your legal rights nor release the investigators or involve agencies from their legal and professional responsibilities.

Thank you for your time and cooperation.

Consent for Interview today, measurement of Refrigerator Temperature and a second visit : three or four months:

Participant's Signature

Witness

Date

Appendix F

Letters of Introduction from Medical Officers of Health



Eastern Newfoundland Regional Community Health

P.O. Box 70
Holyrood, NF
A0A 2R0

Fax: 709-229-4005

Administration

C.E.O.'s Office
709-229-4855
Business Office/
Purchasing
709-229-4124
Human Resources
709-229-3973

Community Health Client Services

Public Health Nursing
Home Care
Home Support
Rehabilitation
709-229-4812
708-229-3352

Health Promotion/ Protection

Communicable Disease
Control
Environmental Health
Nutrition
Health Education
Child Health
709-229-3367

Mental Health &
Addictions Services
709-229-3353

February 24, 1998

Dr. [REDACTED]
Medical Clinic
P.O. Box 299
Kelligrews, NF
A0A 2T0

Dear Dr. [REDACTED]

Immunization continues to be the principle method of primary prevention, especially in the prevention of childhood infectious diseases. Physicians play an important role in immunization in Newfoundland and Labrador.

Within the next two months you may be contacted by Catherine O'Keefe, a graduate student in Community Health, Memorial University of Newfoundland who is conducting a study on immunization practices in physician offices in Eastern Newfoundland. The Newfoundland Medical Board, Newfoundland and Labrador Medical Association and the College of Family Physicians are all familiar with this study. The objectives of the study include:

- To assess immunization practices in physician office settings with a focus on storage, handling and documentation in immunization practices.
- To provide information which supports practice guidelines consistent with those of the National Advisory Committee on Immunization.
- To assess the change in practice from the initial visit to the second visit.
- To compare pre and post intervention practice with national guidelines, "National Guidelines of Childhood Immunization" National Advisory Committee on Immunization, December 1997.

Page Two (2)
Letter - Dear Physician
Date: February 24, 1998

A visit to your office will be requested which will take approximately 10-15 minutes of your time. The information will be compiled in study results.

Information on individual practices will not be available in the results, which are expected to be available in late 1998.

We hope to count on your cooperation with this study, which may contribute to improved immunization practices and a healthier population.

Sincerely,

Catherine Donovan, M.D., M.H.Sc.
Regional Medical Health Officer

CD/sd



March 11, 1998

Dear Physician:

Re: Vaccine Study

Within the next two months you may be contacted by Catherine O'Keefe, a graduate student in the Master's Program at Community Health, Memorial University of Newfoundland. Ms. O'Keefe is conducting a study of immunization practices among physicians in our region. A smaller study of this nature was carried out upon physicians in the St. John's area last year, and was well received. The Newfoundland Medical Board, the Newfoundland and Labrador Medical Association and the College of Family Physicians have all been consulted regarding this project.

The main focus of this study will be to collect data on vaccine handling before and after information on the National Advisory Committee on Immunization guidelines has been provided. An office visit of between 10 and 15 minutes will be requested. Summary information on the study results will be available to participants.

I hope you will consider participation in Ms. O'Keefe's study. Should you have any questions, please be in touch.

Yours sincerely,

ANN ROBERTS M.D.
Medical Officer of Health
Assistant Executive Officer

Appendix G

Intervention Materials



COMMUNICABLE DISEASE REPORT

Province of Newfoundland and Labrador

Vol. 18, No. 3

March 1996

VACCINE STORAGE, TRANSPORTATION AND WASTAGE

Storage and Transportation

In the June 1995 issue of the Canadian Communicable Disease Report, National guidelines for vaccine storage and transportation were released. Maintaining vaccine at the optimal temperature (2° to 8° C) from the time it leaves the manufacturer until administration (maintaining the cold chain) is a major issue for those who provide immunization programs. When the cold chain is interrupted there is a possibility of reduced vaccine effectiveness, vaccine failure, an increase in local reactions post immunization, and increased vaccine wastage. In summary:

To keep vaccine at proper temperature:

- Keep refrigerated.
- Refrigerate as soon as it is received from the shipper.
- Do NOT store on the door of the refrigerator or near the freezer section.
- The refrigerator should not be used for anything else (eg. lunches).
- Refrigerator doors should be opened only as often as necessary, and for only as long as necessary.
- The freezer compartment should be kept ice free.
- Ice packs should be stored in the freezer section and water bottles should be stored on the doors and lower area to stabilize temperature.
- Make sure door is closed when not in use.
- Space products to allow for circulation of air.

One person appointed for vaccine management should:

- Be trained regarding the importance of maintaining proper temperature.
- Do two temperature readings every work day and record same.

Other vaccine related concerns:

- One person responsible to have a procedure in place to maintain cold chain in the event of power outage or refrigerator failure.
- If vaccine is returned due to possible exposure to heat or freezing, refrigerate in a box labelled DO NOT USE until exposure is checked and advice obtained regarding use.
- A poster with information on cold chain should be posted in all vaccine storage areas.

- Complete regular maintenance of equipment with recording of same.
- Place a sign near the plug of the refrigeration unit and electrical outlet to ensure the unit does not become unplugged.

For those requiring specific information on transportation of vaccine please refer to CCDD Vol. 21 11 p. 95 - 96.

Vaccine Wastage

The total vaccine wastage for Newfoundland and Labrador for the five year period 1990 - 1994 was approximately four to six percent of the total dollars spent on vaccine annually. While this is a significant amount it appears to be low compared to other provinces who have researched this area.

A vaccine wastage report was done for the Department of Health in 1995. Many of the recommendations of this report were similar to those found in the national recommendations for storage and transportation which have been discussed in the previous section. Some other recommendations have been made specifically regarding vaccine wastage. they include:

- Vaccine users should order and stock only the amount needed.
- Return soon-to-be expired vaccine for redistribution in health unit.
- Provide information for all personnel involved in vaccine handling and storage (including public health nurses, physicians, clerical and cleaning staff).
- Place a poster on the storage unit with facts regarding vaccine storage.
- Ensure the availability of adequate packing and storage materials, including: ice packs, insulated vaccine bags, styrofoam boxes, cold and hot monitors for en route packaging (for long distance transport).
- Use couriers who have been informed of the importance of maintaining the proper temperature.

The recommendations discussed here are also included in the Newfoundland and Labrador Immunization Manual p. 8.3-2.

Cost per dose of commonly used vaccines (1996)

DPT & Act-HIB	\$18.10	Td & Polio	\$ 8.35
Influenza	\$ 1.77	Hepatitis B (1 ml)	\$17.35
MMR	\$ 8.21	Rabies vaccine	\$62.14

References:

Evaluation of Vaccine Wastage. Disease Control and Epidemiology, Department of Health: April 1995.
National Guidelines for vaccine storage and transportation. CCDD 1995: Vol 21-11 : p 93 - 103.



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An Advisory Committee Statement (ACS)

Français

National Advisory Committee on Immunization (NACI)*

GUIDELINES FOR CHILDHOOD IMMUNIZATION PRACTICES Canada Communicable Disease Report -

Volume 23 (ACS-6), 1 December 1997

Adobe Downloadable Document  (86 KB)

PREAMBLE

The National Guidelines for Childhood Immunization Practices have been developed by the National Advisory Committee on Immunization (NACI) through an extensive consultation process. They are an integral part of achieving our national goals and targets for vaccine-preventable diseases of infants and children. The purpose of these guidelines is to achieve a standard of practice that will ensure vaccines are handled properly and delivered to all children as recommended by provincial and territorial programs.

*Immunization is a major cornerstone in our efforts to improve the health of people all over the world. It was responsible for the global eradication of smallpox in 1977 and the elimination of paralytic poliomyelitis in the western hemisphere as certified by the Pan American Health Organization in 1994. Vaccine-preventable diseases have experienced a tremendous decrease in Canada, demonstrating the effectiveness of existing provincial and territorial programs, and the successful role played by private and public providers. Compared to the pre-vaccine era, the Canadian achievements have been remarkable: over a 95% decrease in the incidence of many diseases - measles, invasive infections due to *Haemophilus influenzae* type 1, and the complete elimination of polio.*

Outbreaks of vaccine-preventable diseases occur, however, as highlighted by recent epidemics of measles and pertussis. In addition, cases of congenital rubella syndrome continue to occur. These have been attributed largely to inadequate immunization in certain populations. The increase in pertussis cases in Canada over recent years, the importation of wild polio virus in 1993 and 1996 into Canada and the diphtheria epidemic in Eastern European countries remind us that the risk for these diseases still exists despite current programs, and that the level of protection of the population must be kept as high as possible.

The value of immunization has been definitely established. One tends to take its benefits for granted and its very success leads to complacency. We no longer see the devastating effects of vaccine-preventable diseases. Moreover, because of the low frequency of occurrences, the apparent balance of risks and benefits begins to shift towards a greater perception of the risks. The unfortunate implication is that more people may abandon or even oppose immunization. A recent national survey revealed that the public was well informed by health-care providers about the risks of side effects but less informed about the benefits of receiving vaccines.

Some of the established national goals and targets have been achieved and good progress is being made towards the others, but much effort is still needed to reach them all.

Several factors point to the need for National Guidelines for Childhood Immunization Practices.

- Population-based estimates of vaccination coverage for 2-year-olds in Canada show areas for concern. Coverage for four doses of pertussis, tetanus and diphtheria vaccine was 87% versus a target of 95%. In addition, there is no coverage for groups that oppose vaccination on religious grounds, and coverage is unknown for the am...

influx to Canada of about 60,000 newcomers < 18 years of age.

- There are missed opportunities for vaccination in Canada, resulting in preventable morbidity and mortality. In 19 and 1994, respectively, 17.5% and 25.0% of cases with *Haemophilus influenzae* type b infection occurred in children who were eligible to receive vaccine but did not - some as a result of parental decisions not to immunize but others as a result of inappropriate deferral of immunization or failure to give the vaccine as recommended.
- Some provincial studies indicate that up to 13% of vaccines were exposed to freezing during distribution and storage.
- The reporting of vaccine-associated adverse events varies widely across jurisdictions in Canada.

The continued success of routine childhood immunization requires that all those involved, including policy makers, program administrators, and providers take a pro-active approach to childhood immunization, and work together to achieve and maintain a high standard of excellence in planning, conducting, and reviewing childhood immunization programs.

NACI embarked on a process of developing guidelines for childhood immunization practices which could be applied to current public and private systems for vaccine delivery. The guidelines were first drafted in 1995. They were revised after 2 years of consultation with provincial and territorial health authorities; professional medical, nursing, public-health, and hospital organizations; individual providers; and child advocacy groups; and discussion at the 1996 National Immunization Conference. They have been endorsed by the Canadian Paediatric Society, Health Canada's Advisory Committee on Epidemiology, the College of Family Physicians of Canada, the Canadian Medical Association, the Canadian Nurses Association, the Aboriginal Nurses Association of Canada, and the Society of Obstetricians and Gynaecologists of Canada.

The guidelines are deliberately broad, far-reaching, and rigorous. Defined as directing principles, they represent the most desirable immunization practice. Providers can use them to assess their current practices, and to identify areas of excellence as well as areas requiring improvement. Some of the guidelines require the involvement of the provinces and territories (e. the need to track immunizations and audit coverage levels). Furthermore, some providers and programs may not have the necessary funds to implement the guidelines fully at this time. In such cases, the guidelines can act as a tool to better define immunization needs, and to demonstrate the need for additional resources to achieve national goals and targets.

These guidelines are recommended for use by all health professionals in the public and private sectors who administer vaccines or manage immunization services for infants and children. Some of the guidelines will be more applicable to particular settings or situations but all should be considered in reviewing current practices.

Certain terms have been used throughout. "Provider" refers to any individual, nurse, or physician qualified to give a vaccine. The individual usually responsible for a given child's routine immunization is referred to as the "regular immunization provider". Given the variations in practices and populations across Canada, it is understood that there may be no identifiable regular provider in some cases and the term may encompass a collective group in other cases. "Child" or "children" is used to refer to individuals, from infancy through adolescence, being considered for immunization, as prescribed by routine immunization schedules. Terms such as "client" and "patient" have not been used but could be considered interchangeable with "child" in the text. "Parent" is used throughout to designate the individual(s) legally responsible for the child and includes both parents as well as legal guardians.

Ideally, immunization should be part of comprehensive childhood health-care programs to ensure that children of all ages are up-to-date with recommended schedules. The delivery of primary care to infants, children, and adolescents and routine immunization in Canada is done in a variety of settings - from physicians' offices to public-health clinics. Private providers and local health officials should cooperate in their efforts to assure high coverage rates in the community to achieve and maintain the highest possible degree of community protection against vaccine-preventable diseases.

On behalf of the collaborating groups, we ask for your full cooperation in striving to follow these guidelines for childhood immunization practices.

GUIDELINES FOR CHILDHOOD IMMUNIZATION PRACTICES

GUIDELINE 1*Immunization services should be readily available.*

Immunization services should be responsive to the needs of parents and children. When feasible, providers should schedule immunization appointments in conjunction with appointments for other health services for children. Immunization services, whether public-health clinics or physicians' offices, should be available during the week and at hours that are convenient for working parents. Services should be available on working days, as well as during some other hours (e.g. weekends, evenings, early mornings, or lunch hours).

GUIDELINE 2*There should be no barriers or unnecessary prerequisites to the receipt of vaccines.*

While appointment systems facilitate clinic planning and avoid unnecessarily long waits for children, appointment only system may act as barriers to the receipt of vaccines. Children who appear on an unscheduled basis for vaccination should be accommodated when possible. Such children should be rapidly and efficiently screened without requiring other comprehensive health services.

A reliable decision to vaccinate can be based exclusively on the information elicited from a parent, and on the provider's observations and judgment about the child's wellness at the time. At a minimum, this includes

- asking the parent if the child is well
- questioning the parent about potential contraindications (Table 1)
- questioning the parent about reactions to previous vaccinations
- observing the child's general state of health.

Policies and protocols should be developed and implemented so that the administration of vaccine does not depend on individual written orders or on a referral from a primary-care provider.

GUIDELINE 3*Routine childhood immunization services should be publicly funded.*

All routine childhood immunizations, as recommended by NACI, should be considered necessary medical services. As such, they should be provided at no charge to patients under provincial and territorial health-service systems.

GUIDELINE 4*Providers should use all clinical encounters to screen for needed vaccines and, when indicated, vaccinate children.*

Each encounter with a health-care provider, including those that occur during hospitalization, is an opportunity to review the immunization status and if indicated, administer needed vaccines. Physicians who offer care to infants and children should consider the immunization status at every visit and offer immunization service as a routine part of that care or encourage attendance at the appropriate public health or physician clinic. At each hospital admission the vaccination record should be reviewed, and before discharge from the hospital, children should receive the vaccines for which they are eligible by age or health status. The child's current immunization provider should be informed about the vaccines administered in hospital. However, successful implementation requires significant improvements in keeping records of immunization histories (see Guideline 2).

GUIDELINE 5*Providers should educate parents in general terms about immunization.*

Providers should educate parents in a culturally sensitive way, preferably in their own language, about the importance of vaccination, the diseases vaccines prevent, the recommended immunization schedules, the need to receive vaccines at recommended ages, and the importance of bringing their child's vaccination record to every health-care visit. Parents should be encouraged to take responsibility for ensuring that their child completes the full series. Providers should answer all questions parents may have and provide appropriate education materials at suitable reading levels, preferably in the parents' preferred

language. Providers should familiarize themselves with information on immunization provided by the appropriate health departments as well as other sources.

GUIDELINE 6

Providers should inform parents in specific terms about the risks and benefits of vaccines their child is to receive.

Information pamphlets about routine childhood vaccines are available from ministries of health in many provinces and the territories, and also from the Canadian Paediatric Society. Such pamphlets are helpful in answering many questions that parents may have about immunization. Providers should document in the medical record that they have asked the parents if they have any questions and should ensure that satisfactory answers to any questions were given.

Providers should explain where and how to obtain medical care during daytime and nighttime in case of an adverse event following vaccination.

GUIDELINE 7

Providers should recommend deferral or withholding of vaccines for true contraindications only.

There are very few true contraindications to vaccination according to current Canadian guidelines and providers must be aware of them. Accepting conditions that are not true contraindications often results in the needless deferral of indicated vaccines.

Minimal acceptable screening procedures for precautions and contraindications include asking questions to elicit a history of possible adverse events following prior vaccinations, and determining any existing precautions or contraindications (Table 1).

Table 1: Contraindications and precautions for childhood vaccines[±]

Vaccines	True Contraindications	Precautions [±]	Not Contraindications
All vaccines	Anaphylactic reaction to previous vaccine dose		Mild to moderate local reactions following injection of vaccine
	Anaphylactic reaction to vaccine constituent		Mild acute illness with or without fever
	Moderate or severe illness with or without fever		Current antimicrobial therapy
			Convalescent phase of illness
			Prematurity
			Recent exposure to infectious disease
			Personal or family history of allergy, except personal history of anaphylaxis to one or more vaccine components
DPT	Anaphylactic reaction to previous dose of vaccine	Hypotonic-hyporesponsive state within 48 hours of prior dose of DPT	History of pertussis
			Fever $\geq 40.5^{\circ}\text{C}$ after prior dose of DPT
			Family history of sudden infant death syndrome
			Convulsion within 48 hours of prior dose of DPT
			Family history of convulsions

OPV	Infection with HIV or household contact with HIV	Pregnancy	Persistent, inconsolable crying lasting ≥ 3 hours, within 48 hours of prior dose of DPT Breast feeding Current antimicrobial therapy Diarrhea
	Immunodeficiency state		
IPV	Immunodeficient household contact		
MMR	Anaphylactic reaction to neomycin	Anaphylactic reaction to egg ingestion Recent IG administration	Tuberculosis or positive PPD Simultaneous TB skin testing Current antimicrobial therapy Infection with HIV Non-specific allergy History of Hib disease Pregnancy Pregnancy
	Pregnancy (Note: The theoretical risk of fetal damage, if any, is very small. Thus rubella immunization in the first trimester should not be a reason to consider termination of pregnancy.)		
	Immunodeficiency state		
Hib			
HBV			
Influenza	Anaphylactic reaction to eggs		

* Adapted from the *Canadian Immunization Guide*, 4th edition, 1993. For further information consult appropriate sections of the guide.

† The events or conditions listed as precautions are not contraindications but should be carefully considered in determining the benefits and risks of administering a specific vaccine. If the benefits are believed to outweigh the risks (e.g. during an outbreak or foreign travel), the vaccine should be given.

GUIDELINE 8

Providers should administer all vaccine doses for which a child is eligible at the time of each visit.

Available evidence indicates that most routine childhood vaccines can be administered at the same visit, safely and effectively. Some vaccines are provided in a combination format whereby more than one is given in a single injection and others require separate injection.

GUIDELINE 9

Providers should ensure that all vaccinations are accurately and completely recorded.

9.1 Data to be recorded in the child's record at the time of vaccination

For each vaccine administered the minimum data to be recorded in the child's record should include the name of the vaccine, the date (day, month, and year) and route of administration, the name of the vaccine manufacturer, the lot number, and the name and title of the person administering the vaccine.

9.2 Updating and maintaining the personal vaccination record

All providers should encourage the parents to maintain a copy of their child's personal vaccination record card and present it at each health-care visit so that it can be updated. If a parent fails to bring a child's card, the provider should ensure that adequate information is given so the parent can update the card with the name(s) of the vaccine(s), the date, the provider and the facility.

9.3 Documentation for vaccines given by other providers

Providers should facilitate the transfer of information in the vaccination record to other providers and to appropriate agencies in accordance with legislation.

When a provider who does not routinely vaccinate or care for a child administers a vaccine to that child, the regular provider should be informed.

GUIDELINE 10

Providers should maintain easily retrievable summaries of the vaccination records to facilitate age-appropriate vaccination.

Providers should maintain separate or easily retrievable summaries of vaccination records to facilitate assessment of coverage as well as the identification and recall of children who miss appointments. In addition, immunization files should be sorted periodically, with inactive records placed into a separate file. Providers should indicate in their records, or in an appropriately identified place, all primary-care services that each child receives in order to facilitate scheduling with other services.

GUIDELINE 11

Providers should report clinically significant adverse events following vaccination - promptly, accurately, and completely.

Prompt reporting of adverse events following vaccination is essential to ensure vaccine safety, allowing for timely corrective action when needed, and to continually update information regarding vaccine risk-benefit and contraindications.

Providers should instruct parents to inform them of adverse events following vaccination. Providers should report all clinically significant events to the local public-health authority, regardless of whether they believe the events are caused by the vaccine or not. Providers should fully document the adverse event in the medical record at the time of the event or as soon as possible thereafter. At each immunization visit, information should be sought regarding serious adverse events that may have occurred following previous vaccinations.

GUIDELINE 12

Providers should report all cases of vaccine-preventable diseases as required under provincial and territorial legislation.

Providers should know the local requirements for disease reporting. Reporting of vaccine-preventable diseases is essential for the ongoing evaluation of the effectiveness of immunization programs, to facilitate public-health investigation of vaccine failure and to facilitate appropriate medical investigation of a child's failure to respond to a vaccine appropriately given.

GUIDELINE 13

Providers should adhere to appropriate procedures for vaccine management.

Vaccines must be handled and stored as recommended in manufacturers' package inserts. The temperatures at which vaccine are transported and stored should be monitored daily. Vaccines must not be administered after their expiry date.

Providers should report usage, wastage, loss, and inventory as required by provincial, territorial or local public-health authorities.

Providers should be familiar with published national and local guidelines for vaccine storage and handling. Providers must ensure that any office staff designated to handle vaccines are also familiar with the guidelines.

GUIDELINE 14

Providers should maintain up-to-date, easily retrievable protocols at all locations where vaccines are administered.

Providers administering vaccines should maintain a protocol that, at a minimum, discusses the appropriate vaccine dosage, vaccine contraindications, the recommended sites and techniques of vaccine administration, as well as possible adverse events and their emergency management. The Canadian Immunization Guide and updates, along with package inserts, can serve as references for the development of protocols. Such protocols should specify the necessary emergency equipment, drugs (including dosage), and personnel to manage safely and competently any medical emergency arising after administration of a vaccine. All providers should be familiar with the content of these protocols, their location, and how to follow them.

GUIDELINE 15

Providers should be properly trained and maintain ongoing education regarding current immunization recommendations.

Vaccines must be administered only by properly trained persons who are recognized as qualified in their specific jurisdiction. Training and ongoing education should be based on current guidelines and recommendations of NACI and provincial and territorial ministries of health, the Guidelines for Childhood Immunization Practices, and other sources of information on

immunization.

GUIDELINE 16

Providers should operate a tracking system.

A tracking system should generate reminders of upcoming vaccinations as well as recalls for children who are overdue for their vaccinations. A system may be manual or automated, and may include mailed or telephone messages. All providers should identify, for additional intensive tracking efforts, children considered at high risk for failing to complete the immunization series on schedule (e.g. children who start their series late or children who fall behind schedule).

As an added measure, providers should encourage the development of, and cooperation with, a comprehensive provincial and territorial immunization tracking system.

GUIDELINE 17

Audits should be conducted in all immunization clinics to assess the quality of immunization records and assess immunization coverage levels.

In both public and private sectors, an audit of immunization services should include assessment of all or a random sample of immunization records to assess the quality of documentation, and to determine the immunization coverage level (e.g. the percentage of 2-year-old children who are up-to-date). The results of the audit should be discussed by providers as part of their ongoing quality assurance reviews, and used to develop solutions to the problems identified.

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[LCDC] [Contact] [Français]

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Canada

Appendix H

Telephone Protocol

Code _____

Script for initial contact (2-3 minutes)

*Hello, my name is Cathy O'Keefe and I am a graduate student at Memorial University of Newfoundland, Community Health. My research is related to Immunization. Does your office provide childhood immunizations. Yes No
(If yes) I would like to make an appointment to visit your office for 10-15 minutes in the next month or so. When would be the most convenient date and time for you.*

Date : _____

Time: _____

If no or not sure if Dr will be able

Would it be o'kay for me to call back later ?

I will leave my number if there is any change: 753-1349 (home number)

Script for Second visit: (5-10 minutes)

Have you had any questions or concerns about the information left on the last visit?

On Storage and Handling:

On Documentation:

If consent was given, may I measure your refrigerator temperature ? _____

Do you have any other comments:

Appendix I

Vaccine Associated Adverse Events Form

PLEASE PRINT OR TYPE ANY FOLLOW-UP INFORMATION		FULLY DELIVERED <input type="checkbox"/>		FATAL <input type="checkbox"/>		LOST TO FOLLOW-UP <input type="checkbox"/>		PENDING <input type="checkbox"/>	
SOUGHT MEDICAL ATTENTION (Emergency room, clinic, family physician etc.)		NO <input type="checkbox"/> YES <input type="checkbox"/>		(If yes, include relevant details of treatment under Supplementary Information)					
HOSPITALIZED BECAUSE OF EVENT(S)		NO <input type="checkbox"/> YES <input type="checkbox"/>		LENGTH OF STAY (DAYS)		DATE ADMITTED		Year Month Day	
CONCOMITANT MEDICATIONS (exclude those used to treat the adverse event)				MEDICAL HISTORY					
.RUG(S) GIVEN				Please provide information on relevant medical history or concurrent illness (See detailed instructions on reverse)					

SUPPLEMENTARY INFORMATION

INSTRUCTIONS FOR COMPLETING REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

1. Please use dark ink when completing form to improve legibility of copies.
2. Report only events which have a temporal association with a vaccine and which cannot be attributed to co-existing conditions. **A causal relationship does not need to be proven, and submitting a report does not imply causality.**
3. Events marked with an asterisk (*) must be diagnosed by a physician. Supply relevant details in the SUPPLEMENTARY INFORMATION box.
4. Record interval between vaccine administration and onset of each event in minutes, hours or days.
5. Provide relevant information, when appropriate, in the SUPPLEMENTARY INFORMATION box. Includes details of events diagnosed by physician (see 3 above), results of diagnostic or laboratory tests, hospital treatment, and discharge diagnoses where a vaccinee is hospitalized because of a vaccine-associated adverse event. If appropriate, and preferred, photocopies of original records may be submitted.
6. Provide details of medical history that are relevant to the adverse event(s) reported. Examples include a history of allergies in vaccinee, previous adverse event(s), and concurrent illnesses which may be associated with the current adverse event(s)

TO BE COMPLETED BY MEDICAL HEALTH OFFICER RECOMMENDATIONS FOR FURTHER IMMUNIZATION

NAME: _____		PHONE: _____		SIGNATURE _____		DATE		Year Month Day	

